IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

MARIA TREVINO,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-01617

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

For reasons appearing to the court, it is **ORDERED** that the Memorandum Opinion and Order (*Daubert* Motions) [ECF No. 106] is **VACATED**. I enter the current Memorandum Opinion and Order to provide additional clarity on certain experts.

Throughout these MDLs, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of an expert's testimonial opinion may be evaluated at trial. At trial, the opinions will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven

related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert opinion testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert opinions offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalization of opinions, and incomplete deposition transcripts. This, combined with the parties' practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it is only achievable through live witnesses at trial and I therefore reserve ruling until expert opinions can be evaluated firsthand.

Pending before the court are the following motions brought by the defendant: (1) Motion to Exclude the Opinions and Testimony of Niall Galloway, M.D. [ECF No. 32]; (2) Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [ECF No. 30]; (3) Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [ECF No. 33]; (4) Motion to Limit the Opinions and Testimony of Bobby L. Shull, M.D. [ECF No. 39]; (5) Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [ECF No. 40]; (6) Motion to Exclude the Opinions and Testimony of Peggy

Pence, Ph.D. [ECF No. 43]; (7) Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [ECF No. 44]; (8) Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [ECF No. 45]; (9) Motion to Limit the Opinions and Testimony of Dionysios Veronikis, M.D. [ECF No. 36]; (10) Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [ECF No. 47]; (11) Motion to Exclude the Opinions and Testimony of David Goldfarb, M.D. [ECF No. 41]; and (12) Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [ECF No. 55].

Also pending before the court are the following motions brought by the plaintiff: (1) Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [ECF No. 34]; (2) Motion to Exclude Certain Opinions and Testimony of Dr. Patrick Culligan [ECF No. 38]; (3) Motion to Exclude or Limit the Testimony Christine Brauer, Ph.D. [ECF No. 37]; (4) Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. [ECF No. 35]; (5) Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 53]; (6) Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 54]; and (7) Motion to Exclude the Opinions and Testimony of Dr. Michael Douso [ECF No. 29].

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the

seven MDLs, there are more than 75,000 cases currently pending, approximately 19,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. In this particular case, the plaintiff, Maria Trevino, was surgically implanted with the Uphold Vaginal Support System ("Uphold"), a mesh product manufactured by BSC to treat POP, and the Prefyx PPS System, a mesh device manufactured by BSC to treat SUI. Ms. Trevino received her surgery at St. Luke's Patient's Medical Center in Pasadena, Texas, on December 28, 2009. Short Form Compl. 4 [ECF No. 1]. She now claims that, as a result of the implantation of these devices, she has experienced various complications and injuries. The plaintiff advances the following claims against BSC: negligence; strict liability for design defect, manufacturing defect, failure to warn; breach of express and implied warranties; discovery rule, tolling, and fraudulent concealment; and punitive damages. *Id.* The parties have retained experts to render opinions regarding the elements of these causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Rule 702 of the Federal Rules of Evidence, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education" and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data;" and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The Supreme Court has established a two-

part test to govern the admissibility of expert testimony under Rule 702: the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper. "[E]xpert witnesses have the potential to be both powerful and quite misleading," so the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999); *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested;" (2) whether the theory "has been subjected to peer review and publication;" (3) the "known or

potential rate of error;" (4) the "existence and maintenance of standards controlling the technique's operation;" and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94). Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("[T]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." (citation omitted)); *Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevance, the second part of the analysis, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (citations and quotation marks omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable

leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

III. Preliminary Matters

I begin by addressing a few preliminary matters that affect many of the *Daubert* motions. First, both parties consistently challenge experts' opinions as improper state-of-mind or legal-conclusion testimony. As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding expert opinions on the defendant's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics). The reasonableness of conduct and a party's then-existing state of mind "are the sort of questions that lay jurors have been answering without expert assistance from time immemorial," and therefore, these matters are not appropriate for expert testimony. *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998); *see also In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.").[1] Likewise, "opinion testimony

[1] On a related note, I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—he or she may not be offered solely as a conduit for corporate information. There is no reason why the plaintiffs require an expert to opine on such facts.

that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). An expert may not state his opinion using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

I have diligently applied these rules to previous expert testimony, and I continue to apply them in this case. This does not mean that each objection to state-of-mind or legal-conclusion testimony raised in these motions is valid. But I will not parse the numerous reports and thousand-page depositions for each expert to determine the validity of these same objections. Instead, the onus is on counsel to tailor expert testimony at trial in accordance with the above directive. Therefore, unless otherwise necessary, the remainder of this opinion does not address objections brought against an expert based on improper state-of-mind or legal-conclusion testimony.

I also note that several of the *Daubert* motions concern expert opinions entirely unrelated to the individual plaintiff at bar. For example, some experts have opined on general and specific causation with the specific causation portion of the opinion pertaining to wave plaintiffs other than Ms. Trevino. In addition, the parties filed a total of seventeen *Daubert* motions involving, in many instances, duplicative experts. In an effort to remedy this problem of blanketed, duplicative *Daubert* motions, I directed the parties to file disclosures, indicating who, out of the seventeen challenged experts, they plan to call at trial for each case. *See* Pretrial Order No. 121, at 5–6

[ECF No. 56]. Through these disclosures, I hoped to gain a better understanding of the particular arguments at issue, thereby refining my *Daubert* rulings for the benefit of the receiving judge. Rather than aiding the court in this endeavor, however, the parties effectively ignored the pretrial order, identifying *all seventeen* of the challenged experts as probable expert witnesses. *See* BSC's Disclosure Required by Pretrial Order No. 121 [ECF No. 57]; Pl.'s Disclosure Required by Pretrial Order No. 121 [ECF No. 58]. Without guidance from the parties to the contrary, I have thus limited my review of the *Daubert* motions to only those arguments and opinions related to the instant plaintiff. In other words, I disregard arguments included in the briefing directed exclusively at other wave plaintiffs and, consequently, irrelevant to Ms. Trevino's case.

Finally, I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of an expert's opinion based on its reliability and relevance. In other words, the parties have comparatively examined each expert's opinions and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that

I align with these previous rulings when faced with a different record are remiss, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert opinions and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular opinions and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the opinions contained therein.

IV. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude the expert opinions of Drs. Niall Galloway, Michael Thomas Margolis, Thomas H. Barker, Bobby L. Shull, Jimmy W. Mays, Peggy Pence, Russell Dunn, Scott Guelcher, Dionysios Veronikis, Richard Trepeta, David Goldfarb, and Vladimir Iakovlev.

A. Niall Galloway, M.D.

Dr. Niall Galloway is an Associate Professor of Surgery (Urology) at the Emory University School of Medicine in Atlanta, Georgia, whose practice consists largely "of handling complications resulting from the placement of synthetic mesh in the vagina for POP and SUI." Galloway Report 2 [ECF No. 32-1]. On behalf of Ms. Trevino, Dr. Galloway offers a general causation opinion, which BSC now seeks to exclude.

1. Biomaterials

First, BSC argues that Dr. Galloway is not qualified to opine on biomaterials and that his opinions are unreliable. With regard to his qualifications, BSC points to Dr. Galloway's deposition testimony where he states that he is not an expert in biomaterials. BSC's Mot. re: Galloway 5 [ECF No. 32]. However, this testimony is not dispositive. *See Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *36 (S.D. W. Va. July 8, 2014) (finding Dr. Johnson qualified to opine about polypropylene notwithstanding his deposition testimony). I have previously found certain medical doctors qualified to opine as to polypropylene. *See* Mem. Op. & Order 6–9, *Jones v. Bard, Inc.*, No. 2:11-cv-00114 [ECF No. 391] (finding Dr. Ostergard qualified to opine as to polypropylene and product design); *see also Huskey*, 2014 WL 3362264, at *35–37 (finding Dr. Johnson qualified to opine as to mesh degradation).

Like the physicians in these prior cases, Dr. Galloway is an accomplished urologist with years of experience treating pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. *See* Pl.'s Resp. re: Galloway 6–7 [ECF No. 75] ("His opinions are founded on a deep understanding

of anatomical processes as they related to permanent surgical implants, along with his clinical observations from performing hundreds of revision and removal procedures involving mesh."). Dr. Galloway's clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction. Accordingly, BSC's motion with regard to Dr. Galloway's qualifications is **DENIED**.

BSC also contends that Dr. Galloway's opinions are unreliable. However, the only support BSC offers for this contention is a portion of Dr. Galloway's deposition where he states that he cannot recall whether he reviewed BSC's biocompatibility testing. BSC's Mot. re: Galloway 6–7. Dr. Galloway's failure to review BSC's biocompatibility testing does not sufficiently undermine the reliability of his opinions and is an issue better suited for cross-examination. Accordingly, BSC's motion with regard to the reliability of Dr. Galloway's biomaterials opinions is **DENIED**.

2. Material Safety Data Sheet ("MSDS")

Next, BSC argues that Dr. Galloway is not qualified to opine on the Medical Application Caution contained in the MSDS for the polypropylene resin used to manufacture the Uphold. Specifically, BSC seeks to exclude two of Dr. Galloway's opinions on this topic:

> (1) I have seen no evidence that Boston Scientific disclosed this information to doctors and patients, nor did Boston Scientific seek further information, or do appropriate testing to determine the validity of these warnings. This is information that doctors and patients are entitled to know and need to know in order to make informed decisions regarding treatment options. Without complete and accurate information, informed consent is not possible.

> (2) In my opinion, placing a material that degrades, releases potentially toxic chemicals, creates a chronic inflammatory response, and was advised against by the manufacturers of the raw component represents a serious flaw in the design of Boston Scientific's transvaginal mesh devices.

Galloway Report 9–10. With regard to Dr. Galloway's first opinion, his discussion of BSC's corporate conduct will not be helpful to the jury and is thus **EXCLUDED**. However, Dr. Galloway is qualified, as a physician, to opine that information regarding the Medical Application Caution is critical to the informed consent process. With regard to the second opinion, Dr. Galloway is not using his "scientific, technical, or other specialized knowledge" to make the factual statement that the manufacturers of polypropylene advised against permanent use, as BSC purports. Fed. R. Evid. 702. Instead, Dr. Galloway is using the information provided in the Medical Application Caution to support his opinions on the Uphold's design, which, as discussed more fully *supra*, he is qualified to provide. Accordingly, the remainder of BSC's motion with regard to the MSDS is **DENIED**.

3. Design & Adequacy of Warnings

Next, BSC contends that Dr. Galloway is not qualified to opine on the design or adequacy of warnings of polypropylene transvaginal mesh devices. With regard to design, BSC highlights Dr. Galloway's lack of experience implanting the Uphold or any other polypropylene transvaginal mesh device. However, I agree with the plaintiff that Dr. Galloway's experience *removing* polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him in this case. Furthermore, Rule 702 does not necessarily require specific clinical experience

implanting the device at issue. *See Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989) ("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion."); *see also Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *4–5 (S.D. W. Va. July 8, 2014) (finding expert qualified to offer general causation opinions despite his lack of specific experience with the product at issue). Accordingly, BSC's motion with regard to Dr. Galloway's opinions on product design is **DENIED**.

With regard to warnings, BSC only points to one "inadmissible" opinion: "By alphabetizing [complications in the Uphold's Directions for Use ("DFU")], rather than listing in order of importance (as is the convention), BSC further trivializes the importance of these adverse events." Galloway Report 28–29. In support of exclusion, BSC highlights Dr. Galloway's lack of familiarity with FDA regulations and requirements for warnings. This argument is unpersuasive because Dr. Galloway does not appear to rely on the FDA in arriving at his opinion. Upon independent review, however, I nevertheless find that Dr. Galloway's opinion regarding alphabetization is nothing more than his personal belief. Although Dr. Galloway states that listing complications in order of importance is "convention," he fails to provide any basis for this statement. Therefore, the court has no way of assessing its reliability. Accordingly, BSC's motion with regard to warnings is **GRANTED**, and this opinion is **EXCLUDED**.[2]

[2] To the extent BSC seeks to exclude other warnings opinions, I find that as a urologist, Dr. Galloway is qualified to testify about the risks of implanting the Uphold and whether those risks were adequately expressed in the Uphold's DFU. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to

4. Risk/Benefit Analysis

Next, BSC contends that Dr. Galloway provides no factual basis for his opinion that the risks of polypropylene always outweigh the benefits. In support of its position, BSC cites a portion of Dr. Galloway's deposition testimony where he states "that there are situations, although rare, in which the benefits might outweigh the risks." Galloway Dep. 174:7–8, Dec. 17, 2014 [ECF No. 32-9]. The opinion BSC seeks to exclude comes from the section of Dr. Galloway's report discussing his review of the literature on transvaginally placed surgical meshes. *See* Galloway Report 19–23. Drawing on his clinical experience and review of relevant literature is a sufficiently reliable method of forming an opinion that the risks of polypropylene outweigh the benefits. For purposes of *Daubert*, the fact that Dr. Galloway acknowledges the mere possibility of a situation where a particular patient might benefit from transvaginal mesh surgery does not undermine his overall opinion, which he clarifies by stating "that for the great majority of patients, the long-term risks do outweigh the benefits." Galloway Dep. 174:11–13, Dec. 17, 2014. Accordingly, BSC's motion with regard to Dr. Galloway's risk/benefit analysis is **DENIED**.

5. Polypropylene Degradation

Next, BSC argues that Dr. Galloway provides no basis for his opinion that polypropylene degrades. Specifically, BSC objects to the conclusions that Dr. Galloway makes based on the *Clave* study. Here, Dr. Galloway considered and

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opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . ." (internal quotations and brackets omitted)).

analyzed multiple scientific articles—not just the *Clave* study—and drew on his clinical experience to reach his opinion that polypropylene degrades. This is a reliable, scientific methodology. *See Monsanto Co. v. David*, 516 F.3d 1009, 1015 (Fed. Cir. 2008) ("[N]umerous courts have held that reliance on scientific test results prepared by others may constitute the type of evidence that is reasonably relied upon by experts."). Any inconsistencies or discrepancies in his testimony go to its weight, not its admissibility, and BSC is free to capitalize on these matters during cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). Accordingly, BSC's motion with regard to polypropylene degradation is **DENIED**.

6. Trocars

Next, BSC contends that Dr. Galloway's opinions on trocars, the instrument used to implant certain transvaginal mesh devices, should be excluded because the implantation of the Uphold does not require the use of a trocar. In response, the plaintiff concedes that Dr. Galloway's opinions related to the use of trocars will only be offered if the case involves the use of a trocar. Accordingly, BSC's motion with regard to trocars is **DENIED as moot**.

7. Relevant Literature

Lastly, BSC argues that Dr. Galloway's opinions are not tied to the facts of this case because he only reviewed one scientific article that specifically references the Uphold. As discussed more fully *infra* in relation to Dr. Badylak, if there are certain

device-specific publications that Dr. Galloway failed to review in preparing his expert report, BSC is free to inquire about those publications on cross-examination. Accordingly, BSC's motion with regard to literature is **DENIED**.

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Niall Galloway, M.D. [ECF No. 32] is **GRANTED in part** and **DENIED in part**.

B. Michael Thomas Margolis, M.D.

BSC seeks to exclude the testimony of Michael Thomas Margolis, M.D. Dr. Margolis is a pelvic floor surgeon and urogynecologist who offers general causation opinions in this case. *See* Margolis Report 1–26 [ECF No. 30-1]. BSC argues that his opinions are unreliable because he failed to consider contrary scientific literature and failed to provide any scientific basis for his other opinions. Also, BSC argues that Dr. Margolis seeks to offer opinions beyond his expertise.

1. Failure to Consider Studies

BSC argues that Dr. Margolis failed to consider contrary scientific studies in forming his opinions, making his opinions unreliable. An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*; *see also Abarca v. Franklin Cty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different

sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (quoting *Dwyer ex rel. Dwyer v. Secretary of Health and Human Serv.,* No. 03–1202–V, 2010 WL 892250, at 148 (Fed. Cl. Mar. 12, 2010))); *Rimbert v. Eli Lilly & Co.*, No. 06-0874, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009) *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable."). BSC's challenge is threefold.

First, BSC argues that Dr. Margolis's opinion that polypropylene mid-urethral slings are not safe and effective for the treatment of SUI is unreliable because he ignored peer-reviewed literature indicating otherwise. The defendant specifically argues that Dr. Margolis simply disregarded studies that were not supportive of his opinions (i.e., the Rosenblatt abstract and the Nilsson data). Also, while Dr. Margolis agrees that there is scientific literature supporting the use of polypropylene mid-urethral slings to treat SUI, the defendant argues that Dr. Margolis failed to identify such literature.

Dr. Margolis testified that he was concerned that the Rosenblatt abstract could be the result of skewed data. Margolis Dep. 234:7–17. Dr. Margolis stated, "I am concerned when a physician who has a strong, intense financial conflict of interest publishes anything . . . ." *Id.* at 232:3–5. Dr. Margolis also testified that he did not

support the Nilsson study for three reasons: (1) the authors got paid only if they concluded that TVT mesh was effective and safe, (2) the study was not safety-specific, and (3) thirty-five percent of the original cohort of patients were lost to follow-up in the seventeen-year study. *Id.* at 218:15–219:19.

Dr. Margolis has explained his methodology for giving less credence to certain studies than to others. Dr. Margolis states that he has examined other studies that counter his own opinions. To the extent the defendant challenges the reasons Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis's opinions, not their admissibility. The defendant is free to cross-examine Dr. Margolis regarding studies that cut against his opinions. The defendant's motion is **DENIED** on this point.

Second, BSC challenges Dr. Margolis's opinion that there is a greater than 50 percent complication rate of pain in women with polypropylene mesh and slings. BSC contends that he fails to provide a scientific basis for disagreeing with studies that find lower pain rates. Dr. Margolis merely discounts those studies "[b]ecause that's not what [he] ha[s] seen, read, studied, observed, and that's not biologically plausible." *See* Margolis Dep. 239:11–13, Jan. 6, 2014 [ECF No. 34-2].

In his deposition, Dr. Margolis acknowledges that contrary studies exist, *see id.* at 239:2–6, and I do not doubt that Dr. Margolis reviewed contrary studies. However, his methodology may be flawed if he does not provide an adequate explanation for why he disagrees with those studies. The plaintiff has failed to identify such an explanation in this case. Therefore, Dr. Margolis's opinion that more

than 50 percent of women implanted with mesh experience pain is **EXCLUDED** as unreliable. This aspect of BSC's motion is **GRANTED**.

Third, BSC challenges Dr. Margolis's general opinions that complications in women with polypropylene mesh products are high. BSC contends that Dr. Margolis disregards literature revealing single digit dyspareunia complication rates without sufficient explanation. In his deposition, Dr. Margolis discounts these studies by alleging that the complications are underreported, the studies are inaccurate, and the data is possibly fabricated. *Id.* at 241:12–20. Moreover, Dr. Margolis explains that, when forming his opinion about the complication rates of a medical procedure, he "give[s] the benefit of the doubt to the patient." *Id.* at 259:8–9. In other words, he "assume[s] the worse-case scenario" and errs on the side of opining as to a higher complication rate to better protect a patient. *Id.* at 259:11–29. This is not a reliable, scientific basis for determining the complication rates associated with a mesh device. *Id.* at 259:8–9. The plaintiff has failed to demonstrate that Dr. Margolis has sufficient scientific support to opine as to these generalized statements. Therefore, this testimony is **EXCLUDED**, and this part of BSC's motion is **GRANTED**.

2. Lack of Scientific Basis

BSC also argues that Dr. Margolis failed to provide any scientific basis for his other opinions. The plaintiff does not address the majority of BSC's arguments on this point. Instead, in a generalized fashion, she states in a paragraph that Dr. Margolis should be allowed to testify about his personal experience. Pl.'s Resp. re: Margolis 13–14 [ECF No. 83]. BSC interprets this response as the plaintiff's

concession. I decline to raise counterarguments for the plaintiff when she has failed to address BSC's arguments in her briefing. The plaintiff has not "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Therefore, the following opinions from Dr. Margolis are **EXCLUDED**: (1) that the Burch procedure is more effective than polypropylene mesh slings; (2) that Xenform slings are more effective than polypropylene slings; (3) that the infection rate of polypropylene mesh is up to 100 percent; (4) that the complication rate of urethral obstruction is greater than 10 percent with polypropylene mid-urethral slings; and (5) that he has removed 10 to 15 percent of BSC products. These portions of BSC's motion are **GRANTED**.[3]

Unlike the above opinions, the plaintiff appears to respond to BSC's argument concerning Dr. Margolis's opinion about a lack of scientific support for the use of mesh. In his report, Dr. Margolis opines that there is a lack of sound scientific data supporting the use of mesh in the treatment of both SUI and POP. Margolis Report 21.[4]

[3] I have previously excluded Dr. Margolis's opinions (2) through (5) on reliability grounds. *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *16-18 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *see Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014) (addressing only opinions (3) and (5)). In *Sanchez*, a POP case, I excluded opinion (1) on relevancy grounds. *See Sanchez*, 2014 WL 4851989, at *15.

[4] I note that BSC's motion challenges this opinion with respect to SUI only, even though this case involves both SUI and POP products. BSC's Mem. re: Margolis 6 [ECF No. 31]. However, the plaintiff in her response and BSC in its reply argue as if BSC had challenged this opinion with respect to POP, as well. The court will accept the parties' interpretation and analyze this opinion as it relates to POP.

As for the reliability of this opinion with respect to SUI and POP, BSC contends that Dr. Margolis's opinion should be excluded because Dr. Margolis contradicted himself during his deposition. In response, the plaintiff argues that BSC misinterprets Dr. Margolis. The plaintiff contends that Dr. Margolis merely opines that there is a lack of *long-term* data. Contradictions in testimony should be addressed on cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994) ("[E]valuating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses . . . ."). Therefore, I do not exclude Dr. Margolis's opinion on a lack of *long-term* data on reliability grounds.[5] Therefore, BSC's motion regarding this opinion is **DENIED**.

3. Expertise

BSC argues that Dr. Margolis offers opinions outside the scope of his qualifications on "(1) biomaterials; (2) polypropylene degradation; (3) foreign body reaction; (4) adequate pore size; (5) adequate weight of polypropylene; (6) biocompatibility of polypropylene; (7) medical device design and development; and/or

[5] The plaintiffs in prior cases have responded to this same challenge in a different way. *See Sanchez*, 2014 WL 4851989, at *14; *Tyree*, 54 F. Supp. 3d at 519–27; *Eghnayem*, 57 F. Supp. 3d at 676–80. Instead of focusing on long-term data, those plaintiffs informed the court that Dr. Margolis never opined that there was *no* data supporting the benefits of polypropylene mesh, but just that there was no *credible* data on this subject. In those cases, I excluded Dr. Margolis's opinion because "it [was] still unclear why Dr. Margolis believe[d] th[o]se studies lack[ed] credibility." *Sanchez*, 2014 WL 4851989, at *14.

(8) marketing." BSC's Mem. re: Margolis 15 [ECF No. 31]. In her response, the plaintiff states that "[t]o the extent that Dr. Margolis' opinions regarding biomaterials, medical device design, development, and marketing are outside of his expertise and experience, Dr. Margolis will be instructed to limit his opinion and avoid these areas. However, plaintiff['s] stipulation is only as to these limited areas outside of his expertise." Pl.'s Resp. re: Margolis 14 [ECF No. 83].

In its reply, BSC states that this concession is "unclear." Reply re: Margolis. 5 [ECF No. 88]. I find that the plaintiff's response explicitly concedes that Dr. Margolis will not offer opinions on topics (1), (7), and (8). Further, the remaining topics—(2) through (6)— fit within at least one of the categories listed by the plaintiff. Resp. re: Margolis 14. In terms of the concession's qualifying language (i.e., to the extent these subjects are outside of Dr. Margolis's expertise, "Dr. Margolis will be instructed to limit his opinion and avoid these areas") the court declines to engage in analyzing the plaintiff's intentional ambiguity. *Id.* The plaintiff fails to provide any argument addressing how Dr. Margolis is an expert on any of the above subject matters, beyond the basic assertion that "Dr. Margolis is an established urogynecologist with years of experience with pelvic mesh products." *Id.* I need not make such arguments for them. Therefore, this aspect of BSC's motion is **GRANTED**.

4. Undisclosed Opinions

Finally, BSC argues that Dr. Margolis seeks to offer opinions that were not disclosed in his expert report and that Dr. Margolis seeks to discuss materials that were not cited to in his expert report. Rule 26 of the Federal Rules of Civil Procedure

requires an expert report to contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). The plaintiff does not provide a response to this argument.

BSC argues that Dr. Margolis cited at his deposition "to a power point presentation and over 16 new articles that were not included in his report or the attachments thereto." BSC's Mem. re: Margolis 17 [ECF No. 31]. BSC attaches to its motion a list of five deposition transcripts, one U.S. Patent Publication, thirty-six BSC documents, and forty-two scientific articles that were not included in Dr. Margolis's expert report or relied-upon list. Margolis Nondisclosure List Ex. G, at 1–4 [ECF No. 30-2]. Testimony on direct examination using such undisclosed sources as support for his opinions is **EXCLUDED** on Rule 26 grounds. However, the court notes that two articles that BSC alleges were not disclosed—*Vaginal Mesh Contraction: Definition, Clinical Presentation and Management* and *Surgical Management of Pelvic Organ Prolapse in Women*—were included in Dr. Margolis's relied-upon list. *See* Margolis Report App. B, at 1–68 [ECF No. 30-1]. Dr. Margolis's testimony on these two articles is not excluded under *Daubert*.[6] Therefore, I find that this aspect of BSC's motion is **GRANTED IN PART** and **DENIED IN PART**.

For the reasons stated above, I **GRANT in part** and **DENY in part** BSC's Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [ECF No. 30].

[6] BSC also states that any opinions that Dr. Margolis based on Laura Angelini's deposition should be excluded because the transcript "was not produced and plaintiffs' counsel would not agree to produce it." BSC's Mem. re: Margolis 18. I decline to exclude these opinions on Rule 26 grounds. Laura Angelini's deposition is listed in Dr. Margolis's relied-upon list attached to his Rule 26 expert report. Margolis Report App. C, at 1. Whether or not the plaintiffs' counsel will provide BSC with this transcript is a discovery matter.

C. Thomas H. Barker, Ph.D.

BSC seeks to exclude the testimony of Thomas H. Barker, Ph.D. The plaintiff offers Dr. Barker as a biomaterials expert. He seeks to testify as to general opinions, such as those related to the biocompatibility of polypropylene mesh, mesh degradation, scar formation, mesh design, and mesh testing. *See* Barker Report 4–7 [ECF No. 33-1]. BSC argues that Dr. Barker's opinions are unreliable because he lacks sufficient scientific support and because his opinions are litigation driven. BSC also contends that Dr. Barker is unqualified to opine on polypropylene generally and on design and testing. In forming his opinions, Dr. Barker relied upon the scientific literature, his experience, and corporate documents.

1. Reliability

a. Mechanical Mismatch

Dr. Barker opines that there is a mechanical mismatch between vaginal tissue and BSC mesh. *See, e.g.*, Barker Report 5. I find this opinion to be unreliable. In comparing the elastic moduli of vaginal tissue to that of mesh in order to support his opinion as to a mismatch, Dr. Barker relied on a study finding six to seven kilopascals for vaginal tissue. Barker Dep. 84:13–16, Dec. 15, 2014 [ECF No. 33-1]. However, he admits that he has no scientific basis for forming a kilopascal number for BSC mesh. *Id.* at 105:3–14. Moreover, Dr. Barker admits that, although "[t]here's significant evidence in the medical literature that there are regimes that the mesh is not mechanically matched with vaginal tissue . . . the studies were never done, so we can't say for sure." *Id.* at 108:10–22. He also testifies that "there's certainly data to suggest

that the mesh gets significantly stiff under load" but then concedes that, "without proper testing, it's everyone's guess." *Id.* at 13–14. Such an opinion rests on an unreliable basis. To the extent that Dr. Barker merely opines that vaginal tissue and polypropylene mesh are not composed of the same material, such an opinion is not helpful to a jury. Dr. Barker's opinion that a mechanical mismatch exists is **EXCLUDED**.

b. Mechanical Performance Findings

Dr. Barker's opinions on the clinical consequences resulting from the alleged mechanical mismatch between the mesh and the human body are **EXCLUDED** as unreliable as well. *See, e.g.*, Barker Report 6–7. His opinion on the mechanical mismatch generally is excluded, and, thus, any derivative opinions are also unreliable. Dr. Barker testified that testing would need to be done in order to determine the effect that an implant may have in vivo. *See* Barker Dep. 97:21–1, Dec. 15, 2014. However, he also states that no one has performed this testing for transvaginal mesh. *See id.* at 98:2–7. Concluding that mesh degrades, deforms, or causes scarring in the human body based on speculation that there is a mechanical mismatch between vaginal tissue and BSC mesh fails to survive *Daubert* scrutiny. Moreover, in forming these in vivo opinions, Dr. Barker relied on a mesh study performed ex vivo, where the authors explicitly state that their study does not conclusively reveal the mesh's behavior in the human body. *See* JP Shepard et al., *Uniaxial Biomechanical Properties of Seven Different Vaginally Implanted Meshes for Pelvic Organ Prolapse*, 23 Int'l Urogynecology J. 613, 619 (2012) [ECF No. 93-1]

(stating that "the experimental setup allows us to draw only preliminary conclusions about the various meshes"). Such opinions are too speculative to be deemed reliable under *Daubert*.

Moreover, with respect to mesh deformation in particular, BSC challenges Dr. Barker's opinion that BSC testing revealed approximately 35 percent to 52 percent of deformation in its mesh samples. Barker Dep. 135:14–136:3, Dec. 15, 2014. Dr. Barker bases this opinion on a BSC email. However, when questioned about this topic, Dr. Barker admitted that he is unsure whether this testing was done exclusively on BSC products. *See id.* at 137:15–138:2. This deposition testimony further reveals the unreliability of Dr. Barker's methodology. BSC's motion with respect to Dr. Barker's opinions on the clinical effects of a mechanical mismatch between BSC mesh and vaginal tissue is **GRANTED**.[7]

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [ECF No. 33] is **GRANTED**.[8]

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[7] In her response, the plaintiff contends that BSC does not challenge Dr. Barker's opinions "that the mesh used in the BSC products was not designed to maintain its properties when placed in the body" and that the "biocompatibility of a specific biomaterial is specific to a particular area of the body, which will respond in its own particular fashion." Resp. re: Barker 11 [ECF No. 71]. However, this statement is incorrect. BSC addresses these two opinions in its original motion when challenging Dr. Barker's opinions on the clinical significance of a mechanical mismatch.

[8] BSC also challenges Dr. Barker's qualifications. I do not doubt Dr. Barker's qualifications in the field of biomedical engineering. However, I need not address them because I find Dr. Barker's opinions to be unreliable. Even if an expert is highly qualified, an analysis of the reliability of that expert's methodology is required. *See Daubert*, 509 U.S. at 597 (explaining that the Federal Rules of Evidence "do assign the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"). Qualifications alone do not guarantee reliability. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3–5 (S.D. W. Va. Oct. 11, 2007) (excluding opinions of a "very qualified" expert because the basis for the testimony was unreliable). "[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method." *Daubert*, 509 U.S. at 590.

D. Bobby L. Shull, M.D.

Dr. Bobby Shull is a urogynecologist offered by the plaintiff to provide expert opinion testimony on the design and labeling of the Uphold. BSC moves to exclude several of Dr. Shull's opinions on *Daubert* grounds.

1. Product Design

First, BSC argues that Dr. Shull's opinions on the design of the Uphold should be excluded because they lack a reliable basis. Specifically, BSC argues that Dr. Shull reached opinions on the improper design of the Uphold without having first considered BSC's design protocols. Therefore, in BSC's view, Dr. Shull cannot opine on (1) the Uphold's "departure" from traditional surgeries, (2) BSC's failure to "follow its own internal protocols," or (3) BSC's lack of due diligence in the design and development of the Uphold. Mot. re: Shull 7 [ECF No. 39]. In response, the plaintiff contends that Dr. Shull's opinions regarding the design of the Uphold, while perhaps not based on BSC's design protocols, have a reliable foundation because he considered other sources, such as literature, other BSC internal documents, and his "extensive clinical experience." Resp. re: Shull 9 [ECF No. 78].

Reliance on literature and experience is not dispositive here because the court must also ensure that the expert has reliably applied his methodology to the facts of the case with "the same level of intellectual rigor that characterizes the practice of an expert in [that] field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). Dr. Shull's opinion cannot survive. Dr. Shull admitted that he has never "seen any standard operating procedures" for BSC's medical device development nor has he

seen Boston Scientific's design protocols. Shull Dep. 256:23–257:8, Dec. 11, 2014 [ECF No. 78-3]; *see also id.* at 255:18–23.

Put simply, regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from Dr. Shull's methodology. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were departures from the norm, not followed by BSC, or lacking in any way. Therefore, these three opinions—listed as opinions (2), (11), and (12) in Dr. Shull's expert report—are **EXCLUDED**, along with any other opinions concerning BSC's design protocols.[9]

2. Product Testing

BSC also challenges Dr. Shull's opinions concerning the testing performed on the Uphold, again claiming that Dr. Shull lacks the qualifications necessary to opine on this issue. In response, the plaintiff points to Dr. Shull's extended career as a pelvic floor surgeon. Experience as a surgeon alone, however, does not translate into experience with or knowledge about the appropriate testing a medical device manufacturer should undertake when preparing a product for the market. *See, e.g.*, *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *17 (S.D. W. Va. July 8, 2014) (excluding the opinions of Drs. Blaivas and Rosenzweig on the topic of medical device premarket testing because their work as urogynecologists and urologists does not give them knowledge on product testing). And there is no

[9] Because I find these opinions unreliable, I do not consider Dr. Shull's qualifications in the area of product design. *See* Fed. R. Evid. 702 (requiring an expert witness to be "qualified as an expert" *and* to base his testimony on "reliable principles and methods").

indication in Dr. Shull's expert report or otherwise that he has additional experience with product testing or clinical trials that sets him apart from the average pelvic surgeon on this particular matter. Accordingly, because Dr. Shull has no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices, his opinion falls short of Rule 702's requirements and cannot be admitted. *See* Fed. R. Evid. 702 (stating that an expert must be qualified . . . by knowledge, skill, experience, training, or education"). Any opinion concerning BSC's product testing, or lack thereof, is **EXCLUDED**.

3. Opinions on Product Labels

Next, BSC asserts that Dr. Shull is not qualified to opine on the adequacy of the Uphold's DFU, and even if he was qualified, his opinion on this issue lacks a reliable basis. With respect to Dr. Shull's qualifications, BSC states that Dr. Shull "is not an expert in the regulations or standards that govern [DFUs]; he has never advised a company on a DFU; he is unfamiliar with the industry process governing [DFUs]; and he has not even performed a literature search relating to DFUs." Mot. re: Shull 9. The plaintiff, on the other hand, contends that Dr. Shull will not testify on "*how* BSC *developed* the warning" in the DFU, nor will he opine on the "regulatory requirements or the method or process that is used to develop and approve warnings." Resp. re: Shull 10. Rather, the plaintiff offers Dr. Shull to opine on the completeness and accuracy of the Uphold warnings from a clinical perspective.

Although I agree with BSC that Dr. Shull is unqualified to opine on regulatory requirements and whether the Uphold labels and warnings satisfy those

requirements, the plaintiff has confirmed that Dr. Shull's testimony will not touch on these issues. Instead, Dr. Shull will testify about the risks he perceives that the Uphold poses to patients, and he will opine that that the Uphold DFU did not convey these risks to physicians. A urogynecologist like Dr. Shull is qualified to make this comparison. *See, e.g.*, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *34 (S.D. W. Va. July 8, 2014) (finding Dr. Blaivas, a urologist, qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's DFU); *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs] . . . and to compare that knowledge with what was provided in the text of labeling and warnings . . . ." (quoting *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, at 11 (E.D. Pa. June 20,2000))). I also find that Dr. Shull's forty years of experience, along with his evaluation of medical literature[10] forms a reliable basis for this testimony. *Kumho Tire Co.*, 526 U.S at 156 (stating that "an expert might draw a conclusion from a set of observations based on extensive and specialized experience").

BSC's remaining arguments pertaining to Dr. Shull's labeling opinions go to credibility, not admissibility, and are better suited for cross-examination. Therefore, to the extent that Dr. Shull's opinions on product labeling relate to whether the Uphold DFU conveyed the risks Dr. Shull is aware of, they are not excluded at this

[10] S*ee* Shull Report 4–7 (discussing existing literature on mesh complications).

time. BSC's motion on this issue is **DENIED**.

4. Opinion About the MSDS for Polypropylene Resin

Finally, BSC challenges "Dr. Shull's opinion that he found no evidence BSC inquired into the scientific validity or basis of the MSDS" on the grounds that it is unreliable. Mot. re: Shull 14. To survive *Daubert*, an expert opinion must not be based on "belief or speculation." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999). Here, Dr. Shull attempts to opine that, because he did not find any evidence suggesting BSC inquired into the MSDS, none exists. Such a speculative leap is improper for expert testimony. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). Therefore, this opinion is **EXCLUDED**.

BSC's Motion to Limit the Opinions and Testimony of Bobby L. Shull, M.D. [ECF No. 39] is accordingly **GRANTED in part** and **DENIED in part**.

E. Jimmy W. Mays, Ph.D.

BSC seeks to exclude the expert opinions of Jimmy W. Mays, Ph.D. Dr. Mays is a Distinguished Professor of Chemistry at the University of Tennessee who offers general causation opinions on the following issues: (1) the chemical structure and properties of polypropylene; (2) degradation of polypropylene by thermo-oxidative processes and in vivo; and (3) the effect of in vivo degradation on the polypropylene implant. Dr. Mays's opinions are based upon his experience, knowledge, and references to scientific literature. Additionally, Dr. Mays tested the chemical and thermal properties of seven BSC pelvic repair meshes, including the Uphold, and

compared the results to four commercial isotactic polypropylene resins. Specifically, BSC takes issue with Dr. Mays's thermogravimetric analysis ("TGA"), which is a common method used for studying the thermo-oxidative stability of polymers.[11]

BSC seeks to exclude Dr. Mays's opinions based on his TGA because they are unreliable and irrelevant. By way of background, Dr. Mays performed TGA on seven exemplars in the air and compared their thermo-oxidative stability to that of four commercial polypropylene resins, all of which were stabilized with anti-oxidants. Mays Report 17 [ECF No. 40-2]. Dr. Mays also removed the anti-oxidants from one Pinnacle exemplar to examine how the mesh degraded without stabilization. *Id.* Dr. Mays's results showed that all of the resins degraded in a similar manner. *Id.* Specifically, the specimens started to degrade around 230–250 degrees Celsius and nearly completely degraded at 400 degrees Celsius. *Id.* Dr. Mays noted that the Lynx product showed slightly better thermal stability than the others. *Id.* Based on this testing, Dr. Mays concluded that anti-oxidant stabilizers delay thermo-oxidative degradation, but do not eliminate it; therefore, polypropylene will always degrade in an oxidative environment like the human body. *Id.* at 43.

First, BSC argues that Dr. Mays's opinions should be excluded because his TGA did not replicate the in vivo environment. Specifically, BSC points out that Dr. Mays's TGA was conducted at temperatures well over 200 degrees Celsius when the

[11] As an initial matter, BSC attempts to incorporate by reference its *Daubert* objections to Dr. Mays's general causation opinions offered in *Sanchez v. Boston Scientific Corp.* BSC does not inform the court what these objections are or attach the *Sanchez* motion. Further, the expert report offered in *Sanchez* was authored by both Dr. Mays and Dr. Gido and is not identical to the report offered in the present case. Accordingly, I will not address the objections made in *Sanchez* and instead rule solely on the issues currently before me.

human body is only approximately 37 degrees Celsius. Mot. re: Mays 7 [ECF No. 40] ("TGA merely demonstrates that if you subject a plastic to a high enough temperature in air, it will degrade."). In response, the plaintiff explains that TGA is "not intended to mimic the in vivo environment" but instead "is used as a model and provides predictive information that is particularly useful for product lifetime assessments." Resp. re: Mays 7 [ECF No. 77].

Dr. Mays connects the TGA results to his ultimate conclusions regarding BSC's products in two places in his expert report:

> It should be noted that in the TGA experiments increasing temperature of the polypropylene in the presence of oxygen leads to degradation, which can be delayed but not eliminated by the presence of an anti-oxidant stabilizer packing. Polypropylene degradation also occurs isothermally inside the body. Here, too, polymer degradation may be slowed but not eliminated by the use of antioxidants.
>
> . . . .
>
> Note that polypropylene always undergoes thermo-oxidative degradation in these experiments; the effect of anti-oxidant is only to delay the process. Likewise, the degradation of polypropylene exposed to an oxidative environment, such as the human body, can be delayed but not prevented through use of anti-oxidants.

Mays Report 32, 43. The problem with these conclusions is one of fit and reliability. *See Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."). Dr. Mays produced certain results while testing polypropylene at very high temperatures. He then concludes that the same results will occur inside the human body at much lower temperatures, but he does not provide any explanation or support for his opinion. These derivative conclusions are not the product of reliable principles and methods. "Rule 702's

'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 591–92. Here, Dr. Mays has failed to demonstrate a reliable connection between his TGA results and his conclusions about polypropylene degradation in the human body. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [ECF No. 40] is **GRANTED**, and Dr. Mays's general causation opinions based on his TGA are **EXCLUDED**.[12]

F. Peggy Pence, Ph.D.

Dr. Pence works as a clinical and regulatory consultant, providing "advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the [FDA]." Pence Report 1, Nov. 10, 2014 [ECF No. 43-2].[13] During her career, she has accumulated knowledge about and experience with the testing requirements for medical devices, the development and content of product labeling, and the procedures necessary to comply with regulatory and industry standards, including those set forth by the FDA. *See id.* at 1–5 (listing credentials and experiences). In this matter, Dr. Pence offers four opinions: (1) BSC did not conduct adequate testing of its products prior to placing them on the market; (2) the products were inadequately labeled; (3)

[12] By excluding all of Dr. Mays's TGA opinions as irrelevant, I need not address BSC's arguments regarding the anti-oxidant removal process. *See* Mot. re: Mays 8–9.

[13] Dr. Pence has submitted two expert reports, one focused on SUI products, Pence Report, Dec. 9, 2013 [ECF No. 43-1], and the other focused on POP products, Pence Report, Nov. 10, 2014 [ECF No. 43-2]. The opinions appear to be the same in both reports, and the parties' briefings primarily refer to the most recent version. I follow suit and cite to the November 10, 2014 Report unless the arguments address an opinion stated only in the December 9, 2013 Report.

patients could not adequately consent to the surgical implantation of the products due to the misbranding; and (4) BSC failed to meet the postmarket vigilance standard of care for these products.

Although I have considered these opinions before, Dr. Pence has since updated her expert report, and in response, BSC has refined and reevaluated its objections. I am informed—though not bound—by my previous findings.

1. Qualifications

I first address BSC's argument that this court should exclude Dr. Pence's opinions because she lacks the qualifications necessary to make them. BSC maintains that Dr. Pence's work as a researcher and consultant on the development of medical products does not qualify her to opine about the safety and efficacy of mesh products, as she attempts to do in her expert report. In BSC's view, without a medical degree and without experience in the development of polypropylene mesh, Dr. Pence is unqualified to opine on BSC's medical devices per *Daubert*.

I disagree. The absence of a medical degree on Dr. Pence's curriculum vitae does not call into doubt Dr. Pence's demonstrated knowledge about and experience with medical devices like those at issue. Dr. Pence has over forty years of experience in the research and development of medical devices. Pence Report 1, Nov. 10, 2014. Over that time, she has accumulated knowledge that is relevant to this case, such as the design of clinical trials for diseases of the female genital system, the clinical testing of novel medical devices, and the content of product labeling. Accordingly, I find that Dr. Pence is qualified to render the opinions set forth in her expert report,

including her opinions about the safety and efficacy of mesh products and the sufficiency of BSC's product branding. Having found that Dr. Pence is qualified to offer these opinions, I turn to whether her opinions are relevant and reliable.

2. General Objections

I begin by addressing two objections that BSC raises multiple times throughout its motion, all related to the reliability of the authoritative sources underlying Dr. Pence's opinions, which include a 2006 study by the French National Authority for Health ("HAS"), the recommendations of the National Institute for Health and Care Excellence ("NICE"), and the various guidance documents drafted by the Global Harmonization Task Force ("GHTF").[14] First, BSC argues that because these studies set forth *recommendations* rather than *requirements*, they cannot serve as a reliable basis for Dr. Pence's opinions. BSC, however, has not cited any case suggesting that the binding effect of industry standards dictates their reliability. Indeed, the Seventh Circuit Court of Appeals has suggested the opposite:

> [T]he relevant question for admissibility purposes is not whether the . . . guidelines are controlling in the sense of an industry code, or even how persuasive they are. It is only whether consulting them is a methodologically sound practice on which to base an expert opinion in the context of this case.

Lees v. Carthage Coll., 714 F.3d 516, 525 (7th Cir. 2013). Accordingly, I give no import

[14] The GHTF, which was conceived in 1992 and replaced by the International Medical Device Regulators Forum ("IMDRF") in 2011, represented a "partnership between regulatory authorities and regulated industry" and sought to "achieve greater uniformity between national medical device regulatory systems." IMDRF, *GHTF Archive* 1 [ECF No. 43-5]. The European Union, United States, Canada, Australia, and Japan were the founding members, and these entities, as well as Brazil, China, Japan, and Russia, currently form the Management Committee of the IMDRF. *Id.* Dr. Pence relies on several GHTF "Final Documents" in reaching her opinions. Pence Report Ex. 1, Nov. 10, 2014 [ECF No. 43-5].

to the non-binding nature of the HAS, NICE, and GHTF recommendations in my *Daubert* analysis and instead focus on whether Dr. Pence's reliance on these sources constitutes a methodologically sound practice.[15]

BSC also attempts to equate GHTF standards with FDA regulations and asserts that, like FDA regulations, admission of GHTF standards, which have "regulatory purpose, history, and focus," could confuse and mislead the jury. Mot. re: Pence 10 [ECF No. 43]. Thus, BSC argues that I should exclude Dr. Pence's opinions to the extent they rely on GHTF standards, as I have done with opinions that rely on the FDA. This argument misunderstands my concern with introducing FDA evidence. If I allowed BSC to express to the jury that its product complied with FDA regulations, the jury would then view the product with the gloss of federal-government endorsement. Such a perception of the product is erroneous, given that the product was cleared for market through the FDA's 510(k) process, which "does not in any way denote official approval of the device." 21 C.F.R. § 807.97. GHTF standards, on the other hand, do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. And although the FDA appears to have had a limited role in the activities of the GHTF, that role was not instrumental or definitive, and the work of the GHTF can be described without reference to the FDA. *See generally* IMDRF, *GHTF Organisational Structure*, http://www.imdrf.org/ghtf/ghtf-

[15] That said, because the guidelines that Dr. Pence relies upon are merely recommendations, Dr. Pence is prohibited from expressing to the jury that BSC was "required" to do anything under these standards, which she comes close to doing in her expert report. *See, e.g.*, Pence Report 42, Nov. 10, 2014 ("Premarket Clinical Data Required").

structure.asp (last visited Apr. 4, 2016). Accordingly, I find BSC's argument without merit.

Having disposed of these issues, I now address BSC's arguments with respect to Dr. Pence's opinions on premarket testing, product labeling, and post-market vigilance.

3. Premarket Testing

In her report, Dr. Pence opines:

> BSC should have performed adequate preclinical and clinical testing of the [products] prior to marketing to ensure the devices were reasonably safe for permanent implantation. By its failure to do so, BSC fell below the standard of care required of a reasonably prudent medical device manufacturer.

Pence Report 52, Nov. 10, 2014. In *Sanchez v. Boston Scientific Corp.*, I found this opinion reliable because Dr. Pence was able to support it with "multiple sources that stress the importance of running clinical trials before incorporating mesh materials into a surgical product," namely the HAS study and the NICE recommendations. *Sanchez*, No. 2:12-cv-05762, 2014 WL 4851989, at *34 (S.D. W. Va. Sept. 29, 2014). Here, Dr. Pence again relies on these studies, as well as GHTF standards, to support her opinion that BSC did not conduct appropriate premarket clinical trials.

Generally, BSC contends that none of the studies support Dr. Pence's opinion that BSC should have performed premarket clinical trials. My review of the exhibits, however, indicates that several guidance documents supply a basis for this opinion. For example, the GHTF's *Clinical Evaluation*, which Dr. Pence expanded on during her deposition, Pence Dep. 192:2–197:19, Jan. 10, 2015 [ECF No. 43-5], states that,

prior to placing a device on the market, a manufacturer "must have demonstrated through the use of appropriate conformity assessment procedures that the device complies with the Essential Principles of Safety and Performance of Medical Devices," and part of this process involves analyzing—and sometimes generating—premarket clinical data. GHTF, *Clinical Evaluation* 11, May 8, 2007 [ECF No. 43-5] (illustrating that if the clinical evidence is lacking, a manufacturer should "generate new or additional clinical data"). Another GHTF guidance document states that "[a]t a minimum, tests should be conducted on samples from the finished, sterilized (when supplied sterile) device." Pence Report Ex. 1 ¶ IV, Nov. 10, 2014 [ECF No. 43-5] (quoting GHTF, *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles* § 11 (Feb. 21, 2008)). Additionally, although the NICE and HAS studies are not as explicit as the GHTF documents, they both emphasize the importance of clinical trials in assessing a product's safety for surgical use. *See* HAS, *Evaluation of Mesh Implants Installed Through the Vaginal Approach in the Treatment of Genital Prolapse* 7, Nov. 2006 [ECF No. 84-6] (emphasizing to surgeons "the necessity of using material validated by clinical trials"); NICE, *Surgical Repair of Vaginal Wall Prolapse Using Mesh* ¶ 1.1 [ECF No. 84-7] ("[T]his procedure should only be used with special arrangements for clinical governance, consent and audit or research.").

Furthermore, all of these documents carry the indicia of reliability set forth by *Daubert*: the conclusions were reached after documented and validated testing, the results were published, and the testing was conducted through a defined methodology

described in each paper. *See United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (listing the factors a court might consider when reviewing the reliability of expert testimony under *Daubert*). Therefore, I find Dr. Pence's consultation of these sources in reaching her opinion both justified and reliable.

Next, BSC argues that Dr. Pence's report lacks a "discussion of the [GHTF] standard itself" and "how Dr. Pence's application of that standard led her to form the opinions contained in her report." Reply re: Pence 8 [ECF No. 97]. Dr. Pence's deposition testimony convinces me otherwise:

> I looked at the product, what was known or not known with similar products, what was known historically, what they had done historically in terms of any types of testing, what they did or did not do in terms of testing to move forward and market these products, the same type of analysis and methodology I apply, as I said, with my product development consulting[. B]ased on that information[, I found] that they failed in establishing a favorable benefit-risk ratio because they did not do the appropriate testing and based on the information available to them, they did not have an adequate label to appropriately advise doctors of the information they needed to know . . . . [GTHF] guidance documents state that the products must meet the essential principles of safety and performance. The product must perform as intended to have a . . . favorable benefit-risk ratio. So they needed to do the appropriate testing to establish that.

Pence Dep. 294:17–295:16, Jan. 10, 2015 [ECF No. 84-1]. Based on this testimony, I find that Dr. Pence has satisfactorily applied the GTHF standards—namely *Clinical Evaluation* and *Essential Principles of Safety and Performance of Medical Devices*—to the facts of this case. *See* Fed. R. Evid. 702 (providing that the court must ensure that the expert "has reliably applied the principles and methods to the facts of the case").

BSC's remaining arguments go to the weight of Dr. Pence's testimony, not its

reliability, and are therefore better suited for cross-examination. In conclusion, I **DENY** BSC's motion to exclude Dr. Pence's opinion on premarket clinical testing.

4. Product Labels

Dr. Pence proffers two opinions regarding the labeling of BSC's products. First, she states:

> BSC marketed [the Uphold] without adequate directions for use, notably, without adequate warnings, precautions, and information for implanting surgeons and patients about the extent and likelihood of potential risks, the difficulty of mesh removal and associated morbidity should mesh removal be required, and the potential permanency and life-altering implications of certain risks of mesh removal.

Pence Report 72, Nov. 10, 2014. Second, she states that "patients implanted with the [Uphold] were prevented from being adequately consented [sic] and giving fully informed consent as a result of BSC's inadequate professional and patient labeling." *Id.* at 73. She then offers a list of warnings and risks that she believes should have been included in the products' DFU and patient brochures. *Id.* at 67, 71.

BSC asserts that to the extent these opinions relate to BSC's deviation from the branding requirements of the Food, Drug, and Cosmetic Act ("FDCA"), they should be excluded. I agree. As I have held several times in the course of these MDLs, expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the state tort claims than enlightenment. The jury might think that the FDA regulations *govern* warning requirements in Texas, whereas Dr. Pence is actually using the FDA regulations as a *model* for the contents of labeling material. *Daubert* advises courts to keep in mind the other rules of evidence when evaluating expert testimony, 509 U.S. at 595 ("Throughout, a judge

assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules . . . ."), and applying Rule 403, I find that the probative value of expert testimony on FDA requirements is substantially outweighed by the risk of jury confusion. *See* Fed. R. Evid. 403 (permitting exclusion of relevant evidence if its probative value is substantially outweighed by danger of unfair prejudice, confusion of the issues, or misleading the jury). Furthermore, simply stating that BSC did not comply with FDA regulations is a legal conclusion, not an expert opinion. For these reasons, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (agreeing that "alleged shortcomings in FDA procedures are not probative to a state law products liability claim"). Any opinions arising from Exhibit 1 from Dr. Pence's December 9, 2013 Report [ECF No. 43-5] are **EXCLUDED**.

This finding, however, does not result in the exclusion of Dr. Pence's opinion on product labeling altogether because, unlike in previous cases, Dr. Pence has a second source of information that is unrelated to the FDA (i.e., the GHTF's *Label and Instructions for Use for Medical Devices*) which I must also consider in my analysis. The plaintiff contends that this guidance document serves as adequate and reliable support that is "separate and distinct from FDA and FDCA regulations," and so Dr. Pence's opinion on product labeling survives BSC's *Daubert* challenge. Resp. re: Pence 14 [ECF No. 84]. In response, BSC asserts that, even with the GHTF document, Dr. Pence still lacks support for several of her labeling opinions. Specifically, according to BSC, *Label and Instructions for Use for Medical Devices* does not purport

that a label should contain "information on severity, frequency, and/or permanency of potential adverse events" or "the difficulty of mesh removal," as Dr. Pence opines in her expert report. Mot. re: Pence 14. I agree. The GHTF document on product labels does not state—expressly or otherwise—that manufacturers should include the severity, frequency, and permanency of adverse events in a warning, nor does it state that a label should qualify the difficulty of removing the device. *See* GHTF, *Label and Instructions for Use for Medical Devices* 8–12, Sept. 16, 2011 [ECF No. 43-5] (listing labeling content for medical devices). Furthermore, Dr. Pence does not explain how this document could be interpreted as such. Rather, when pressed on this topic, Dr. Pence admits that the GHTF guidance document does not "get[ ] to that level of specificity." Pence Dep. 261:1–3, Jan. 10, 2015. Seeing no non-FDA grounds for Dr. Pence's opinion that BSC should have included this particular information in its labels, I find it unreliable, and it is therefore **EXCLUDED**.[16]

With respect to Dr. Pence's remaining opinions on product labeling, BSC moves for exclusion because Dr. Pence never spoke to any physicians about this issue. An expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert* so long as the expert has other "sufficient facts or data" to support her opinion. Fed. R. Evid. 702. Here, Dr. Pence considered the GHTF's *Label and Instructions for Use for Medical Devices*, the DFU, several BSC internal documents, and other medical and scientific literature. Pence Report 53–72, Nov. 10,

[16] BSC raises this objection only to Dr. Pence's opinions that the label should have included information on the difficulty of mesh removal and the permanency, severity, and frequency of adverse events. My holding is therefore limited to these specific opinions as well.

2014. I find this collection of sources sufficient for the purposes of *Daubert*. BSC has ample grounds to cross-examine and impeach Dr. Pence at trial regarding any perceived oversights in her analysis.

5. Post-Market Vigilance

In her last opinion, Dr. Pence proffers that BSC "failed to effectively monitor and manage evolving risks with its surgical mesh products for SUI and POP repair and to take appropriate action to minimize patient risk." Pence Report 93, Nov. 10, 2014. BSC argues that this opinion is not helpful to a jury because it is "premised on (1) [Dr. Pence's] review of the adverse events submitted to the FDA's MAUDE Database with respect to the devices at issue and (2) GHTF/IMDRF guidance documents." Mot. re: Pence 16.

In arriving at these opinions, Dr. Pence exclusively considered data from the FDA's MAUDE database.[17] From the database, she compiled and analyzed the complaints and adverse event reports related to the Uphold and concluded that BSC "fail[ed] to report serious adverse events." Pence Report 93, Nov. 10, 2014. As I have previously explained, BSC's communication, or alleged lack thereof, with the FDA through the MAUDE database has "no bearing on whether BSC provided adequate warnings or whether its products were defective." *Sanchez*, 2014 WL 4851989, at *36. Any opinion based on data collected in the MAUDE database, which acts as an arm

[17] "The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers." FDA, *MAUDE—Manufacturer and User Facility Device Experience*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Search.cfm (last visited April 3, 2016).

of the FDA, is not helpful to the jury and is therefore inadmissible. *See* Fed. R. Evid. 702 (stating that the expert's specialized knowledge must "help the trier of fact to understand the evidence or to determine a fact in issue").

The plaintiff responds that, in using the MAUDE database, Dr. Pence "does not proffer opinions about an FDCA or FDA violation" and instead "proffers opinions that establish negligence under state tort law." Resp. re: Pence 15. How and to what end Dr. Pence uses the data is inapposite, however, because further investigation into the MAUDE database reveals that it is unreliable, at least for the purposes of *Daubert*. The MAUDE system is a "passive surveillance system" that does not account for the "potential submission of incomplete, inaccurate, untimely, unverified, or biased data." FDA, *MAUDE—Manufacturer and User Facility Device Experience*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#fn1(last updated Feb. 29, 2016). As such, the data has not been reviewed for accuracy at all, let alone peer-reviewed, and the court has no way to determine the rate of error associated with Dr. Pence's use of it. In addition, given that FDA warns users that the data alone "cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices," *id.*, I can readily conclude that that application of the data to reach a scientific conclusion about a manufacturer's conduct is not generally accepted in the scientific or medical community. Because Dr. Pence's opinion on post-market vigilance appears to be entirely based on data—or lack thereof—found in the MAUDE database, I find it unreliable. Without a reliable basis, Dr. Pence's opinion on BSC's inadequate post-

market vigilance is **EXCLUDED**, and BSC's motion on this matter is **GRANTED**.

6. Final Caveat: Relevance

BSC argues that several of the standards Dr. Pence relies on were not published until after the devices at issue were marketed, making those standards irrelevant to this case. I **RESERVE** ruling on this matter until trial.

In sum, BSC's Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [ECF No. 43] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**. BSC's objection to Dr. Pence's opinions on the alleged carcinogenicity of polypropylene, uncontested by the plaintiff, is **GRANTED**.

G. Russell Dunn, Ph.D.

BSC seeks to exclude the expert opinions of Russell Dunn, Ph.D. Dr. Dunn is a registered professional engineer and the president and founder of Polymer Chemical Technologies LLC, a company that focuses on process and product design issues, process and product safety, and polymer product analysis. Broadly, Dr. Dunn opines that BSC mesh devices are defective because the polypropylene mesh used in these devices undergoes oxidative degradation. BSC contends that Dr. Dunn is unqualified to opine on polypropylene pelvic mesh devices and that the testing he conducted is unreliable.

BSC argues that Dr. Dunn is not qualified to offer opinions concerning the design, risk management, or manufacture of polypropylene mesh devices. In support of this argument, BSC highlights Dr. Dunn's lack of experience with medical devices. In response, the plaintiff first notes that this court rejected certain *Daubert* objections

to Dr. Dunn in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710–11 (S.D. W. Va. 2014). However, Ethicon did not object to Dr. Dunn's qualifications in *Huskey*, as BSC has done here. The plaintiff also contends that the principles Dr. Dunn relies on are not specific to any kind of product but instead apply to the development of polymer products generally, which includes the development of medical devices.

"The fact that a proposed witness is an expert in one area, does not *ipso facto* qualify him to testify as an expert in all related areas." *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 391 (D. Md. 2001) (finding an expert who is a mechanical engineer "not necessarily qualified to testify as an expert on any issue within the vast field of mechanical engineering" and listing numerous cases with similar findings). "Although Rule 702 does not require [Dr. Dunn] to be 'precisely informed about all details of the issue raised in order to offer an opinion,' it also does not provide an open forum for expert testimony that will not assist the trier of fact." *Wright v. Brown*, 993 F.2d 1541, *2 (4th Cir. 1993) (unpublished table decision) (citation omitted) (quoting *Lorillard*, 878 F.2d at 799).

BSC cites to various admissions in Dr. Dunn's deposition evidencing his complete lack of experience with medical devices outside of litigation. Mot. re: Dunn 5–6 [ECF No. 44]. For example, Dr. Dunn's company, Polymer Chemical Technologies LLC, has been involved in over 200 projects focusing on polymer product design; however, none of these projects has involved a medical device. *See* Dunn Dep. 10:12–15, Feb. 21, 2014 [ECF No. 44-1]. Dr. Dunn also teaches five different chemical engineering courses at Vanderbilt University; however, he has never taught a course

specific to medical devices or polypropylene. *See id.* at 12:14–13:6. Similarly, Dr. Dunn states that he has a "tremendous amount of experience" assessing risk through Failure Mode and Effects Analysis ("FMEA"), but then admits that he has "never been involved in developing an FMEA for a medical device." *Id.* at 273:8–25. Finally, Dr. Dunn has authored many publications throughout his career; however, not one of these publications examines medical devices or how polypropylene behaves as part of a medical device. *See id.* at 99:13–20.

All of Dr. Dunn's opinions are premised on his belief that the polypropylene mesh in BSC's devices will undergo oxidative degradation in the body, yet Dr. Dunn admits that he is not an expert in biomaterials or biocompatibility and that he is not qualified to opine on the way polypropylene may affect the body physiologically. *See id.* at 24:17–18, 152:12–14, 153:15–17. Even if Dr. Dunn relies on general engineering principles that apply to polymer products across the board, the opinions set forth in his expert report are clearly outside the scope of basic engineering. *See Shreve*, 166 F. Supp. 2d at 392 ("Unless he is to testify only to general engineering principles that any mechanical engineer would know, the engineer must possess 'some special skill, knowledge or experience' concerning the particular issue before the court." (quoting *Ancho v. Pentek Corp.*, 157 F.3d 512, 517 (7th Cir. 1998))). Unable to draw on some special skill, knowledge, or experience related to medical devices, Dr. Dunn's opinions, including those based on his testing of BSC products, will not be helpful to the trier of fact as required by Rule 702. I find that Dr. Dunn does not have the requisite skill, knowledge, training, education, or experience to qualify as an expert

in this case, and his opinions are **EXCLUDED**. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [ECF No. 44] is **GRANTED**.

H. Scott Guelcher, Ph.D.

BSC seeks to exclude the expert opinions of Scott Guelcher, Ph.D. Dr. Guelcher is a chemical engineer offered by the plaintiff to opine on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant. Broadly, BSC contends that Dr. Guelcher's opinions on oxidative degradation should be excluded because the testing he relies upon—testing completed by Dr. Dunn—is unreliable. As discussed more fully *supra*, I excluded Dr. Dunn as an expert in this case on qualification grounds. Dr. Guelcher's opinions—to the extent they are based on Dr. Dunn's testing—are likewise **EXCLUDED** because Dr. Dunn's testing is unreliable. Dr. Dunn's *in vitro* testing failed to follow the written protocol he relied upon in developing his test—the very protocol that Dr. Guelcher developed. Specifically, Dr. Dunn could not account for why he changed the testing solution once a week when the protocol called for changing the solution once every three days. Mot. re: Dunn 9–13 [ECF No. 44]. Further, Dr. Dunn stated in his deposition that he would only use his testing to show the general behavior of polypropylene mesh in an *in vitro* oxidizing medium—"not to extend what that means inside the body. . . ." Dunn Dep. 227:13–17, Dec. 11, 2014. Dr. Dunn's testing lacks sufficient indicia of reliability. Therefore, BSC's Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [ECF No. 45] is **GRANTED**.

I. Dionysios Veronikis, M.D.

Dr. Veronikis is a urogynecologist who is board certified in female pelvic medicine, reconstructive surgery, and obstetrics and gynecology. Veronikis Report 1 [ECF No. 80-2]. Dr. Veronikis is a diplomat of the American Board of Obstetrics and Gynecology, a fellow of the American College of Obstetricians and Gynecologists, and a fellow of the American College of Surgeons. *Id.* He graduated from the University of Patras School of Medicine and Allied Health Sciences in Patras, Greece, in 1988. Since 1997, Dr. Veronikis has been the Chief of Gynecology and the Director of Vaginal Reconstructive Surgery and Urogynecology at St. John's Mercy Medical Center in Saint Louis, Missouri. *Id.* at 2. Dr. Veronikis is responsible for training general OB/GYN residents in vaginal surgery and urogynecology in the clinic, classroom, and operating room. *Id.* For the past seventeen years, Dr. Veronikis's clinical practice has exclusively focused on vaginal reconstructive surgery and urogynecology. *Id.* Dr. Veronikis has revised or removed over 1100 vaginal mesh products, including vaginal transvaginal mesh slings and prolapse mesh kits. The defendant challenges Dr. Veronikis's qualifications to offer opinions regarding design, testing, and adequacy of warnings, as well as the reliability of these opinions.

a. Design and Testing

The defendant challenges two of Dr. Veronikis's opinions: his opinion about a safer alternative design for the Prefyx, and an opinion about the design process and testing. As to design, Dr. Veronikis opines as follows:

> Boston Scientific was offered a light-weight mesh in 2008, which also would have been a safer alternative design to the Advantage mesh used in Prefyx, in that a lighter mesh has less surface area leading to reduced scar plate formation, reduced inflammation and thus fewer

complications such as chronic pain and chronic dyspareunia.

Veronikis Report 3 (footnotes omitted). Dr. Veronikis bases this opinion on internal BSC documents, his own clinical experience removing over 1000 mesh devices, and a review of the scientific literature that compares the effects of using different mesh materials. *See id.* Dr. Veronikis's opinion on this point is not a critique of the *design process*, but it is an opinion that a *safer* alternative design existed at the time the Prefyx was marketed. Dr. Veronikis's opinion on this issue was based upon a reliable methodology, and he is qualified from his experience, knowledge, and skill to offer such opinions. The defendant's motion on this issue is **DENIED**.

The defendant discusses Dr. Veronikis's general lack of knowledge of BSC's specific design processes by quoting numerous sections of Dr. Veronikis's deposition. In response, the plaintiff points to Dr. Veronikis's extended clinical experience and review of BSC's internal documents. Experience as a practicing urogynecologist alone, however, does not translate into experience with or knowledge about the appropriate testing a medical device manufacturer should undertake when preparing a product for the market. *See, e.g.*, *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *17 (S.D. W. Va. July 8, 2014) (excluding the opinions of Drs. Blaivas and Rosenzweig on the topic of medical device premarket testing because their work as urogynecologists and urologists does not give them knowledge on product testing). And there is no indication in Dr. Veronikis's expert report or otherwise that he has additional experience with product testing or clinical trials that sets him apart from the average pelvic surgeon on this particular matter. Accordingly, because Dr.

Veronikis has no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices, his opinion falls short of Rule 702's requirements and cannot be admitted. *See* Fed. R. Evid. 702 (stating that an expert must be qualified . . . by knowledge, skill, experience, training, or education"). Any opinion concerning BSC's product testing, or lack thereof, is **EXCLUDED**.

b. Adequacy of Warnings

The defendant next argues that Dr. Veronikis's opinions regarding the adequacy of the Prefyx's warnings on its DFU should be excluded because Dr. Veronikis is both unqualified and his methodologies are unreliable. The court does not need to examine Dr. Veronikis's qualifications on this point because the court finds that his opinions are unreliable. Rule 26 of the Federal Rules of Civil Procedure requires an expert to create a written report containing a complete statement of the opinions he intends to express and the basis for them, including the facts and data considered by the witness. Fed. R. Civ. Pro. 26(a)(2)(B). Dr. Veronikis provides several opinions in his expert report regarding the alleged inadequacy of the Prefyx's DFU, and the report clearly includes citations to the DFU. *See* Veronikis Report 5. Perplexingly, however, in his deposition, Dr. Veronikis states that he did not review the DFU while he was preparing his report.

Q. So you did not review the directions for use of the three devices that are at issue with the two patients?

A. Not for my report, I did not.

Q. Probably familiar with those already?

A. I've looked at them for explanting patients, *but I did not use those in my report*.

Q. . . . He's asking if you reviewed them for your deposition as opposed to your report I think.

A. I've looked at them since then, *but I did not have them for my report*.

Veronikis Dep. 11:24–12:11, Nov. 24, 2014 [ECF No. 36-1] (emphasis added). It is clear to the court that offering opinions on the adequacy of a device's DFU without examining them for the expert report is not a reliable methodology. Dr. Veronikis's failure to review the Prefyx's DFU demonstrates that his opinions on the issue are not based upon the very facts needed to form the opinion in the first place. Dr. Veronikis's opinions on this issue are **EXCLUDED**.

2. Reliable Facts and Data

The defendant next argues that certain of Dr. Veronikis's opinions should be excluded because they are not based upon reliable facts and data. The defendant first challenges Dr. Veronikis's initial research methodology. The defendant points out that Dr. Veronikis's research was performed by his research librarian, and this fact, by itself, demonstrates that his opinions are unreliable. The court disagrees. Dr. Veronikis's librarian performed research under Dr. Veronikis's instruction. To the extent that Dr. Veronikis did not continuously check the librarian's work, the issue is best left for cross-examination; it is not a basis for wholesale exclusion of his opinions.

The defendant also argues that Dr. Veronikis summarily dismissed the

Mustafa and Serels studies, which the defendant argues contradicts Dr. Veronikis's opinions. Mot. re: Veronikis 12. But those studies concern the Solyx device only. Merely because Dr. Veronikis did not seriously consider those studies, which concerned a different device, does not justify exclusion of his opinions. The defendant may cross-examine Dr. Veronikis on this point. The defendant's motion on this matter is **DENIED**.

The defendant next argues that Dr. Veronikis's opinions regarding the Prefyx's complication and efficacy rates should be excluded. As support, the defendant argues that Dr. Veronikis should not be permitted to opine that the Prefyx has high complication rates and low efficacy rates because he was unable to provide specific rates of complication and efficacy during his deposition. Mot. re: Veronikis 13–14. Dr. Veronikis, however, cited to three peer-reviewed articles in his expert report to support his opinion. Whether Dr. Veronikis is able to provide specific rates of complication or efficacy goes to the weight of his opinion, and the defendant is free to review the issue on cross-examination. The defendant's motion on this issue is **DENIED**.

The defendant next argues Dr. Veronikis did not provide a basis for his opinions regarding the clinical effects of any shrinkage, degradation, deformation, inflammation, fibrosis, contracture, fraying, rolling, and curling. The defendant also argues that Dr. Veronikis did not consider contrary evidence regarding these issues. Mot. re: Veronikis 14. The specific opinions at issue are the following:

> Boston Scientific's polypropylene mesh products, including [the] Prefyx, are defective in that polypropylene is not inert. Once implanted in the

> human body it shrinks, degrades, deforms, causes chronic inflammation, bridging fibrosis, contracture, fraying, rolling, and curling[,] all of which occur to an unknown degree in each woman's body. The above defects result in scarring, scar encapsulation, and nerve entrapment, all of which lead to chronic pelvic pain, chronic dyspareunia, and de novo urinary symptoms amongst other complications.

Veronikis Report 4.

The defendant argues that "Dr. Veronikis concedes that these phenomena occur 'to an unknown degree' . . . yet he nevertheless attempts to extrapolate mesh complications to these admittedly unpredictable and erratic phenomena." Mot. re: Veronikis 15. Dr. Veronikis, however, cited to several published articles in his report to support this opinions. While Dr. Veronikis acknowledges that the presence of any one of these defects varies from woman to woman at an unknown rate, Dr. Veronikis relied on scientific literature and his own extensive experience to opine that the "sum total" of these alleged defects "creates the problems." Veronikis Dep. 389:2–10. The defendant's challenges go to the weight of Dr. Veronikis opinions, not their admissibility. The defendant's motion on this issue is **DENIED**.

The defendant next argues that Dr. Veronikis is not qualified to offer opinions on the MSDS and his opinions are otherwise unreliable. The court agrees that Dr. Veronikis is not qualified to opine on issues relating to the MSDS. Dr. Veronikis does not possess the requisite knowledge, skill, experience, education, or training necessary to qualify him as an expert witness on MSDS issues. Dr. Veronikis was unable to discuss the relevancy of the MSDS's Medical Application Caution to his opinion. *Id.* at 401:2–16. The court **FINDS** that Dr. Veronikis is not qualified to offer opinions regarding the MSDS. Dr. Veronikis's MSDS opinions are **EXCLUDED**.

The defendant next argues Dr. Veronikis's opinion related to "de-tanging" lacks a reliable scientific methodology. Mot. re: Veronikis 17. Specifically, Dr. Veronikis offer the following opinion:

> BSC "de-tanged" the mid-section of the sling mesh via "hot iron" stating that such may reduce the risk of potential erosion after placement under the urethra. BSC did not provide any clinical evidence to support that statement, nor did BSC indicate the effect of the melting of polypropylene on degradation.

Veronikis Report 5. The defendant's sole argument for excluding the opinion is that "this opinion is litigation-derived and lacks a reliable scientific foundation, as he only formed this opinion *after* he began working on litigation against Boston Scientific." Def.'s Mot. re: Veronikis 17. This court has said that it "will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. But [the court] will consider the independence of an expert's testimony as evidence that his 'research comports with the dictates of good science.'" *Sanchez*, No. 2:12-cv-05762, 2014 WL 4851989, at *4 (quoting *Daubert II*, 43 F.3d at 1317). Dr. Veronikis cites to a published article to support his opinion regarding the relationship between applied heat and polypropylene degradation, *see* Veronikis Report 20 n.103, and the defendant has failed to demonstrate that Dr. Veronikis's opinion on the point is unreliable. Accordingly, the defendant's motion on this issue is **DENIED**.

Therefore, the defendant's Motion to Exclude the Opinions and Testimony of Dionysios Veronikis, M.D. [ECF No. 36] is **GRANTED in part** and **DENIED in part**.

J. Richard Trepeta, M.D.

Richard Trepeta, M.D., is, among other things, a board-certified pathologist

and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease. *See* Trepeta Report 1–2 [ECF No. 76-1]. As part of his fellowship, he "establishes criteria and terminology for the diagnosis of vulvar and vaginal diseases." *Id.* at 2. Dr. Trepeta also examines vulvar-vaginal pathology samples through his private practice. *Id.* In this case, the plaintiff offers Dr. Trepeta to testify as an expert witness on the general pathology of vaginal mesh implantation. *See generally id.* BSC moves to exclude his opinions on the grounds that Dr. Trepeta lacks the qualifications to make them and that his opinions lack a reliable basis.

I have reviewed Dr. Trepeta's opinion, as well as these objections to it, several times throughout the course of this MDL. *See Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *19–24 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 527–532 (S.D. W. Va. 2014); *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 671–676 (S.D. W. Va. 2014). The expert report and *Daubert* objections now before the court are the same as those before the court in previous cases. *See* Resp. re: Trepeta 4 [ECF No. 76] (stating that Dr. Trepeta has not changed his Rule 26 report or his opinions since the *Eghnayem*, *Tyree*, and *Sanchez* rulings). There is no reason for me to depart from my prior holdings.

1. Qualifications

To testify as an expert, a witness must be "qualified . . . by knowledge, skill, experience, training or education." Fed. R. Evid. 702. Although Dr. Trepeta has an impressive background in medicine, BSC argues that his medical training does not

qualify him under Rule 702 to render the opinions he sets forth in his expert reports.

First, BSC objects to Dr. Trepeta's opinion testimony on the properties of polypropylene mesh. In his general report, Dr. Trepeta opines about mesh degradation, mesh contraction, and mesh migration. He states that "[d]egradation occurs as either fragmentation of the mesh or oxidation [of the mesh] release[s] chemical components from the mesh into surrounding tissues," and "[m]esh contraction and shrinkage cause the mesh to be significantly decreased in its physical size." Trepeta Report 5. BSC asserts that Dr. Trepeta is not qualified to offer these opinions because he is not a material scientist, biochemist, or biomedical engineer. Furthermore, he has no training in polymer science or biomedical engineering and has not performed mechanical or chemical testing of mesh products.

In making this argument, however, BSC downplays Dr. Trepeta's knowledge, training, and experience as a clinical pathologist. In general, a clinical pathologist "will be knowledgeable in the areas of chemistry, hematology, microbiology . . . serology, immunology, and other special laboratory studies." 33 Am. Jur. *Trials* 467 § 17 (1986). Dr. Trepeta's thirty years of experience as a clinical pathologist demonstrates sufficient knowledge to provide expert testimony about the chemistry and surgical pathology of materials like transvaginal mesh. Moreover, Dr. Trepeta has knowledge of and experience with pelvic mesh explants in particular, having examined fifty explant samples over the past five years. Trepeta Report 2. Given Dr. Trepeta's knowledge and experience as an anatomical and clinical pathologist, I find him qualified to testify about mesh degradation, mesh shrinkage,

and mesh migration, and I therefore **DENY** BSC's motion in this respect.

Second, BSC objects to Dr. Trepeta's testimony on the human clinical response to mesh implants. Dr. Trepeta opines that the "human body's pathological response to implantation of polypropylene mesh as well as the inherent physical properties of the mesh cause permanent injuries resulting in distortion of the pelvic architecture, sexual dysfunction, persistent pain, scarring, and alteration of bowel and bladder function." Trepeta Report 6. BSC contends that Dr. Trepeta is not qualified to present this opinion because Dr. Trepeta does not treat patients for these conditions and has limited familiarity with the symptoms of SUI and POP. In short, BSC argues that Dr. Trepeta is not a gynecologist, obstetrician, urogynecologist, or a surgeon, and as a result, Dr. Trepeta's opinions about the clinical response to mesh should be excluded.

As I explained in *Sanchez*,

> Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through clinical and pathologic correlation. Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, or physician findings) and reach a pathologic diagnosis about a patient. Dr. Trepeta applied this pathologic process in reaching his conclusions about the human clinical responses to polypropylene vaginal mesh. He examined fifty pathology samples from mesh removals and opines that he observed injuries consistent with the pathological process of tissue response and/or injury due to polypropylene. He also compared medical literature to these observations and concluded that his pathological findings are well described in the published literature. Dr. Trepeta's understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response.

2014 WL 4851989, at *20 (quotation marks and citations omitted). Therefore, I **DENY**

BSC's motion as to Dr. Trepeta's qualifications on this point.

2. Reliability and Relevance

As stated previously, an expert's opinion is admissible if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. BSC raises two objections to the reliability and relevance of Dr. Trepeta's opinion testimony.

a. Reliability

BSC contends that Dr. Trepeta's method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his expert opinion. First, Dr. Trepeta has studied over fifty mesh explant samples in his private practice. Dr. Trepeta received these samples from physicians about once a month over the past five years. Trepeta Dep. 71:8–13, Jan. 25, 2014 [ECF No. 76-2]. He examined these samples under a microscope, identified any abnormalities, and concluded that the samples presented injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." Trepeta Report 2. Second, Dr. Trepeta studied the medical literature on mesh implantation and determined that his pathological findings corresponded with the published research on mesh erosion and exposure in the vaginal wall. *Id.* at 2–3. Third, Dr. Trepeta reviewed twenty-four pathology reports that he received from the plaintiff's counsel and ascertained that "the pathology reports of excised Boston Scientific Products . . . are consistent" with the acute, sub-acute, and chronic categories of the disease process. *Id.* at 4.

BSC's strongest objection to Dr. Trepeta's methodology focuses on this third

source of information. BSC argues that the twenty-four pathology reports were unreliable because they were "hand-picked by Plaintiffs' counsel," Dr. Trepeta only relied on seventeen of the twenty-four reports, and Dr. Trepeta did not review the medical records of any of the probed patients. Mot. re: Trepeta 5–7 [ECF No. 47]. The plaintiff responds that these pathology reports only supplemented Dr. Trepeta's opinion and that the main thrust of Dr. Trepeta's opinion comes from his review of fifty mesh explants over the past five years and from his study of medical literature. Moreover, the plaintiff argues that BSC's chosen expert, Dr. Badylak, agreed that review of pathology reports of vaginal tissue taken from polypropylene explants is an accepted method for reaching a pathologic conclusion on tissue response to polypropylene. Resp. re: Trepeta 4–5 [ECF No. 76].

Acceptance of this practice by experts presented by both parties suggests that this practice is accepted by the general community of pathologists. *See Daubert*, 509 U.S. at 594 ("Widespread acceptance can be an important factor in ruling particular evidence admissible . . . ."). But Dr. Trepeta's review of the pathology reports still has a fatal deficiency—it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. *See id.* (listing as a factor in evaluating an expert's opinion the "existence and maintenance of standards controlling the technique's operation"). The plaintiff does not explain how or why she chose these twenty-four reports for Dr. Trepeta's review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias. *See id.* (stating that the "court ordinarily should consider the potential rate of error"). I confronted a

similar situation in *Lewis v. Ethicon, Inc.* and excluded the expert opinion on hand-selected explant samples because "[t]here are no assurances that [plaintiff's counsel] did not opportunistically choose samples while ignoring others that might have weakened or disproved [the expert's] theories." *Lewis*, 2014 WL 186872, at *8. Here, I similarly have no way to ensure that the plaintiff's counsel did not provide Dr. Trepeta with only those pathology reports that tended to strengthen, rather than refute, Dr. Trepeta's opinions. Accordingly, Dr. Trepeta's opinions derived solely from his review of the twenty-four pathology reports are **EXCLUDED**. BSC is free to cross-examine Dr. Trepeta at trial to ensure the basis of his opinions is consistent with the court's ruling.

b. Litigation Driven

Finally, BSC argues Dr. Trepeta's opinions are unreliable because they are litigation driven. To the contrary, Dr. Trepeta has largely based his opinions on his professional experience with mesh pathology samples examined during his practice. Trepeta Report 2; *see also* Trepeta Dep. 71:6–23 (explaining that over the past five years of his thirty-year practice, he has examined about fifty mesh explants that physicians had sent to him). As I have said before, I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. *Sanchez*, 2014 WL 4851989, at *4. BSC's Motion is **DENIED** on this point.

In conclusion, Dr. Trepeta's general causation opinions are admitted except for his opinions based on the pathologic reports selected by the plaintiff's counsel for his review, which are excluded. Accordingly, BSC's Motion to Exclude the Opinions and

Testimony of Dr. Trepeta [ECF No. 47] is **GRANTED in part** and **DENIED in part**.

K. David Goldfarb, M.D.

David Goldfarb, M.D., is a general urologist with specialized training in minimally invasive surgical techniques. Goldfarb Report 1 [ECF No. 41-2]. He graduated from Baylor University's College of Medicine in 2007, and he completed his residency in urology in 2013 at the same institution.[18] He is currently employed by Houston Metro Urology in Houston, Texas. *Id.* The defendant argues the following opinions should be excluded: (1) general causation opinions on complications associated with polypropylene mesh used to repair POP; (2) the specific causation of the plaintiff's pelvic pain, dyspareunia, pelvic floor dysfunction, and future damages; and (3) the efficacy of the Prefyx. Mot. re: Goldfarb 1–2 [ECF No. 41].

1. POP Mesh General Causation Opinions

The court first acknowledges a few of the plaintiff's concessions contained in her Response. According to the plaintiff, "[t]he only POP mesh general causation opinions Dr. Goldfarb will offer relate to complications caused by POP mesh contraction and scarring. . . . Therefore, many of the various challenges Defendant makes, specifically opinions related to mesh erosion, vaginal bacteria, and mesh degradation, are now moot." Resp. re: Goldfarb 2 (footnote omitted). Accordingly, the court will not examine these issues, and the defendant's motion is **DENIED** as moot.

The defendant first argues Dr. Goldfarb is unqualified to offer general

[18] Dr. Goldfarb stated in his expert report that he completed his residency in 2012; however, he corrected himself in his deposition. Goldfarb Dep. 34:12–16, Dec. 5, 2014 [ECF No. 70-2].

causation opinions regarding polypropylene mesh used for POP repair. The Fourth Circuit applies a liberal approach in determining whether a prospective witness can be qualified as an expert: "The witness' qualifications to render an expert opinion are also liberally judged by Rule 702. Inasmuch as the rule uses the disjunctive, a person may qualify to render expert testimony in any one of the five ways listed: knowledge, skill, experience, training, or education." *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). "Where the expert's qualifications are challenged, 'the test for exclusion is a strict one. . . .'" *Id.* (quoting *Thomas J. Kline, Inc.*, 878 F.2d at 799).

The defendant attacks Dr. Goldfarb's asserted qualifications on the basis that he is thirty-two years old, completed his residency in 2013, and does not have extensive experience handling POP mesh devices or performing POP surgical procedures. Under the law, however, Dr. Goldfarb need not rely on his clinical experience to qualify as an expert. *See Kopf*, 993 F.2d at 377. Dr. Goldfarb graduated in the top 15 percent of his class at the Baylor College of Medicine. Goldfarb Report 2. During his residency, Dr. Goldfarb received specialized training in minimally invasive surgical techniques, including implantation of a variety of mesh products used to treat POP and SUI. *Id.* at 1–2. Since completing his residency, he practices urology as an associate at Houston Metro Urology. *Id.* During the pendency of this litigation, Dr. Goldfarb sat for the written portion of a test for board certification, and he passed in the ninetieth percentile. Goldfarb Dep. 36:1–13. Dr. Goldfarb is on the teaching faculty at the Baylor College of Medicine where he trains urology residents in minimally invasive surgical techniques. *Id.* at 36:18–37:12. Dr. Goldfarb has

performed "somewhere between 44–62 POP procedures utilizing polypropylene mesh." Resp. re: Goldfarb 4 [ECF No. 70]. Dr. Goldfarb has performed roughly ten POP mesh excisions. Goldfarb Dep. 71:6–11. Accordingly, I **FIND** that Dr. Goldfarb possesses sufficient knowledge, skill, education, and training to qualify him as an expert on these issues.

The defendant argues that even if Dr. Goldfarb is qualified, his opinions are otherwise unreliable. The defendant points out that Dr. Goldfarb does not perform POP repairs: "In fact, his practice is to refer all patients suffering from POP to a gynecologist." Mot. re: Goldfarb 5. Dr. Goldfarb has never published or conducted clinical studies on polypropylene, nor has he published or presented on pelvic mesh products or POP treatment. Dr. Goldfarb's only experience with POP repair kits was during his residency when he performed between twelve and twenty POP repairs using vaginal mesh kits. Goldfarb Dep. 41:14–21, 42:12–18; 55:17–56:2; 63:4–7; 89:21–23. As to POP mesh removal procedures, Dr. Goldfarb has performed fewer than ten, and all of those procedures were performed during his residency. *Id.* at 71:1–12.

Dr. Goldfarb's limited clinical experience with POP mesh devices does not, by itself, render his opinions on the subject unreliable. Under Rule 702, Dr. Goldfarb's opinions are reliable if they are based upon sufficient facts or data. Fed. R. Evid. 702(b). The Advisory Committee's note to this provision states that this calls for a "quantitative rather than qualitative analysis." Fed. R. Evid. 702(b) advisory committee's note to 2000 amendments. "The question is whether the expert

considered enough information to make the proffered opinion reliable. . . . The expert must base [his] opinion on at least the amount of data that a reliable methodology demands." 29 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 6268 (2d ed. 1987).

As to Dr. Goldfarb's general causation opinions regarding POP mesh devices, the defendant first argues that Dr. Goldfarb should not be permitted to offer opinions that any mesh contraction is particularly risky for sexually active women. Def.'s Mot. re: Goldfarb 7. Dr. Goldfarb relies on a study to support his opinion that mesh contracts and "is dangerous and more fraught with irreversible risk in the sexually active woman." Goldfarb Report 8. Dr. Goldfarb conceded the study did not examine the same type of mesh applicable to the present case:

> **Q.** Okay. I believe the mesh in that study was less than 75 microns. That's smaller than the pore size of a Type 1 mesh. Isn't that right?
>
> **A.** I believe so.
>
> **Q.** Okay. So would you agree that a larger pore size would allow the mesh to remain more flexible?
>
> **A.** The larger pore size allows for tissue ingrowth, which should allow for kind of a healthier reaction. A lot of the elasticity relates to the amount of mesh and to the density of the mesh. And so it's not just the pore size that's important, but I do understand what you're saying. This is not an identical mesh. This is just a study to show that mesh can have consequences in terms of elasticity.

Goldfarb Dep. 220:20–221:8. Basing an expert opinion on a study for the purpose of showing "that mesh can have consequences in terms of elasticity" when that very study examined mesh of a different type used in the present case is an unreliable

methodology. Accordingly, Dr. Goldfarb's opinion on this issue is **EXCLUDED**.

Relatedly, the defendant next argues that Dr. Goldfarb's opinion that mesh contracts and causes chronic pain and pelvic floor dysfunction is unreliable. Mot. re: Goldfarb 8. The defendant states, "While Dr. Goldfarb cited two studies on hernia mesh repair as support, he failed to establish that hernia mesh studies are, in fact, applicable to POP mesh and, thus, even relevant here." *Id.* The defendant further states, "The mere fact that hernias and POP may both be repaired using various types of mesh does not, by itself, establish that a study on hernia mesh retraction and shrinkage and associated scarring, chronic pain, and pelvic floor dysfunction is at all applicable to POP mesh." *Id.* at 8–9.

Dr. Goldfarb does not attempt to explain how hernia mesh complications in a study involving canines directly relate to POP mesh complications, other than to say that the hernia mesh studies show that mesh can have an "overlying tissue reaction." Goldfarb Dep. 220:20–221:8. Even so, Dr. Goldfarb cites to four studies that actually examined vaginal POP mesh, and he relied on those studies to support his opinion that POP polypropylene mesh contracts, causing chronic pain and dyspareunia. Goldfarb Report 9. I **FIND** that Dr. Goldfarb's general causation opinions regarding contraction, chronic pain, dyspareunia, and pelvic floor dysfunction meet thetest for reliability under *Daubert*. Accordingly, the defendant's motion as to this issue is **DENIED**.

The defendant next argues that Dr. Goldfarb's reliance on a hernia mesh dog study to opine that POP mesh has a shrinkage rate of 30 to 50 percent is unreliable.

During his deposition, the following exchange with Dr. Goldfarb took place:

> **Q.** All right. And are you aware of any studies in women that show a 30 to 50 percent shrinkage rate with polypropylene mesh like that noted in the Klinge report that involved hernia mesh in dogs?
>
> **A.** No. And so that's what I was just going over with you, is that basically the biggest meta analysis that's come out in the gynecologic literature was reported in their committee opinion. And again, there's varying reports, and so they on average say about 11 percent is the rate they expect to see of retracted mesh.

Goldfarb Dep. 222:17–223:2. In essence, Dr. Goldfarb asserts that the Klinge dog study examining hernia mesh supports the Velemir study that examined a "vaginal ultrasound evaluation," which showed "a 50% mesh contraction in 9.3% of patients occurring at only 3 months post-implantation of mesh." Goldfarb Report 9. Dr. Goldfarb provided no explanation in his report to state why hernia mesh contraction or shrinkage in a canine is relevant to alleged vaginal mesh contraction in humans. Accordingly, without any indication that Dr. Goldfarb employed a reliable methodology in forming conclusions about human vaginal mesh shrinkage based on canine hernia mesh shrinkage, such opinions must be **EXCLUDED** under *Daubert*. The court, however, **FINDS** that Dr. Goldfarb's opinions based on the Velemir study, which allegedly showed 50 percent mesh contraction in some instances, are reliable. Accordingly, the defendant's motion on this issue is **DENIED**.

2. Specific Causation Opinions

The defendant next argues that Dr. Goldfarb's specific causation opinions as to the Uphold device should be excluded entirely. Dr. Goldfarb states the following in his expert report: "Based on my experience and training, in my opinion the pelvic

pain, dyspareunia[,] and pelvic floor dysfunction that Ms. Trevino has suffered is a direct consequence of mesh contraction and scar formation following implantation of Uphold polypropylene mesh." Goldfarb Report 10. Dr. Goldfarb conducted a differential diagnosis in making his causation determinations in this case. Dr. Goldfarb personally saw the plaintiff on three separate occasions and took both a physical history and pelvic exam. Goldfarb Dep. 24:7–25:2; 198:8–10. Dr. Goldfarb considered the possible causes for the plaintiff's symptoms and then eliminated each of the potential causes until reaching one that could not be ruled out. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 602. A reliable differential diagnosis passes scrutiny under *Daubert*, and the defendant has failed to demonstrate that Dr. Goldfarb's differential diagnosis is unreliable. The defendant's motion on this point is **DENIED**.

3. Prefyx Efficacy Opinions

The defendant next argues that Dr. Goldfarb's opinions regarding the effectiveness of the Prefyx device should be excluded because it is speculative, unreliable, and unhelpful to the trier of fact. Mot. re: Goldfarb 17. The defendant also argues that Dr. Goldfarb is unqualified to offer efficacy opinions as to the Prefyx because "he has never used, been trained on, [or] even touched a Prefyx." *Id.* at 18. The court does not need to address each of these reasons because Dr. Goldfarb's opinions are both unhelpful and would otherwise confuse, mislead, or present cumulative evidence.

In his report, Dr. Goldfarb states, "The Prefyx midurethral sling is ineffective and, although not helping to resolve her stress urinary incontinence, is not likely to

be the cause of Ms. Trevino's persistent symptoms." Goldfarb Report 11–12. And in his deposition, Dr. Goldfarb states, "The Prefyx is definitely not causing any of her pain complaints . . . based on our encounters together and my physical exam." Goldfarb Dep. 128:19–23. Dr. Goldfarb was retained to offer opinions regarding the cause of the plaintiff's ongoing chronic pain, dyspareunia, and voiding dysfunction. Goldfarb Report 1. As mentioned, Dr. Goldfarb opines that the Prefyx did not cause any of the complications of which the plaintiff is complaining. Accordingly, efficacy opinions regarding the Prefyx are simply not helpful to the trier of fact. Even so, Dr. Goldfarb has neither touched nor seen a Prefyx device. He has relied on two studies, one of which he did not know existed until one of the defendant's experts filed his report. Resp. re: Goldfarb 12 [ECF No. 70]. Finally, when asked whether he thought the Prefyx was not as effective as other slings on the market, Dr. Goldfarb responded, "That's correct. And if it was, I think it would be in more widespread use." Goldfarb Dep. 129:7–11. This lack of facts and data does not meet the standards under *Daubert*. These opinions are **EXCLUDED**.

Therefore, for the reasons stated above, I **GRANT in part** and **DENY in part** the defendant's Motion to Exclude the Opinions and Testimony of David Goldfarb, M.D. [ECF No. 41].

L. Vladimir Iakovlev, M.D.

BSC seeks to exclude the expert opinions of Vladimir Iakovlev, M.D. Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada. Dr.

Iakovlev offers both general and specific causation opinions with regard to the body's response to mesh from a pathologic perspective. BSC argues that Dr. Iakovlev's general causation opinions should be excluded because he relies on specimens other than the plaintiff's. BSC also argues that Dr. Iakovlev's specific causation opinions should be excluded because he did not review the pathology for this particular plaintiff.

1. General Causation

BSC contends that this court should "exclude Dr. Iakovlev's opinions on specimens other than each plaintiff's." Mot. re: Iakovlev 4 [ECF No. 55]. Dr. Iakovlev's general causation opinions are based largely on his examination of the mesh explant samples in his personal data pool. *See* Iakovlev Report 2, 5 [ECF No. 55-2]. However, Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. Dr. Iakovlev testified that plaintiff's counsel provided approximately 70 percent of the transvaginal mesh explants, but he does not know how those explants were chosen or what methodology counsel employed. Iakovlev Dep. 38:12–39:21, Dec. 17, 2014 [ECF No. 79-3]. Dr. Iakovlev "has given no explanation as to whether [his] is a representative sample size or how he chose the particular explants analyzed." *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014). "Therefore, I have no information as to the 'potential rate of error' inherent in [his] observations." *Id.* (citing *Daubert*, 509 U.S. at 594).

In response, the plaintiff contends that Dr. Iakovlev's methodology is sound because it has been subjected to the publication and peer-review process. This past

year, Dr. Iakovlev published two articles in peer reviewed journals about his mesh explant research. *See* Vladimir V. Iakovlev et al., *Pathology of Explanted Transvaginal Meshes*, 8 Int'l J. Med., Health, Biomedical & Pharmaceutical Engineering 549 (2014); Robert Bendavid et al., *Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain*, 5 Int'l J. Clinical Med. 799 (2014). However, "[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability," and is not dispositive. *Daubert*, 509 U.S. at 593–94. In his most recent deposition, Dr. Iakovlev does not explain how the explant samples were chosen and neither do these articles. Therefore, despite publication, the court's concerns with regard to the data pool remain. Likewise, upon review, I find the plaintiff's remaining arguments to be without merit. Accordingly, BSC's motion on this matter is **GRANTED**, and Dr. Iakovlev's general causation opinions based on his data pool are **EXCLUDED**.

2. Specific Causation

It is unclear whether Dr. Iakovlev intends to offer a specific causation opinion in this case because the court has not been provided with an expert report from Dr. Iakovlev specific to this plaintiff. Regardless, BSC indicates that the plaintiff's case is one where Dr. Iakovlev did not review any pathology. Mot re: Iakovlev Ex. 1, at 5 [ECF No. 55-1]. In *Eghnayem v. Boston Scientific Corp.*, I found Dr. Iakovlev's specific causation opinions reliable based on his "morphological differential diagnosis," which included an examination of the plaintiff's explanted mesh. *Eghnayem*, 57 F. Supp. 3d at 675. In this case, there is no evidence that Dr. Iakovlev examined the plaintiff's

explanted mesh or performed a physical examination. Assuming Dr. Iakovlev seeks to offer specific causation opinions, such opinions are not sufficiently reliable under *Daubert* and are thus **EXCLUDED**.

In conclusion, BSC's Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [ECF No. 55] is **GRANTED**.

V. The Plaintiff's *Daubert* Motions

In this case, the plaintiff seeks to limit or exclude the expert opinions of Drs. Gary L. Winn, Patrick Culligan, Christine Brauer, Roger Goldberg, Stephen Spiegelberg, Stephen F. Badylak, and Michael Douso.

A. Gary L. Winn, Ph.D.

The plaintiff seeks to exclude the expert opinions of Gary L. Winn, Ph.D. Dr. Winn is a professor in Industrial and Management Systems Engineering in the Safety Management program at West Virginia University. Dr. Winn offers expert "opinions with regard to the nature and purpose of Material Safety Data Sheets (MSDS) generally, and specifically as to the MSDS for the polypropylene used by [BSC] in the manufacture of its pelvic mesh products." Winn Report 1 [ECF No. 34-1]. The plaintiff argues that Dr. Winn's opinions should be excluded entirely, consistent with this court's decisions in *Tyree* and *Eghnayem* because his expert report is identical to the reports filed and excluded in those two cases.[19] In response, BSC contends that it

[19] In *Tyree*, I ruled as follows:

> In his expert report, Dr. Winn describes (1) the development of the hazard communication standard; (2) the standardization of the content of MSDSs; and (3) uses of MSDSs in the field. Dr. Winn concludes that raw polypropylene is not hazardous based on anecdotal evidence involving other MSDSs; and therefore, the 2004 Chevron Phillips MSDS is extraneous. Although I believe that the warning provided in the MSDS is relevant, I do not believe an

"should be allowed to offer Dr. Winn's testimony and opinions to rebut MSDS related evidence presented by the Plaintiffs at trial." BSC's Resp. re: Winn 17 [ECF No. 69]. Specifically, BSC points to the transcripts from *Tyree* and *Eghnayem* where the plaintiff's experts testified about the MSDS. *Id.* at 15–16.

BSC has not presented any new arguments to convince me that Dr. Winn is warranted as an independent expert. However, I acknowledge the potential need for rebuttal testimony based on what the plaintiff presents at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Winn's expert opinions for trial.

B. Patrick Culligan, M.D.

The plaintiff moves to exclude certain opinions and testimony of Patrick Culligan, M.D. Dr. Culligan is a urogynecologist. Culligan Report 1 [ECF No. 38-2]. In his expert report, he offers nine opinions that relate to polypropylene POP repair products, traditional procedures to treat POP, the risks associated with pelvic surgeries and mesh, BSC's Uphold device, and the Uphold DFU. *See id.* at 18–19. The plaintiff argues that Dr. Culligan's testimony should be limited on qualifications and reliability grounds.

1. Safety and Efficacy

The plaintiff argues that Dr. Culligan's opinions concerning the safety and

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expert is required to discuss MSDSs generally or the issue of whether polypropylene requires an MSDS because of its hazardous nature. A narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning (Medical Application Caution) allegedly not heeded by BSC, not that an MSDS itself existed. This warning from the supplier could have taken any form. Accordingly, I **FIND** that Dr. Winn's opinions regarding MSDSs should be excluded in their entirety.

2014 WL 5320566, at *63; *see also Eghnayem*, 2014 WL 5461991, at *61 (quoting *Tyree*).

efficacy of the Uphold should be excluded because Dr. Culligan's method was unreliable.

First, the plaintiff challenges Dr. Culligan's opinion that the Uphold is safe and effective to treat POP. *Id.* at 18. The plaintiff argues that Dr. Culligan admitted in his deposition that there are only four scientific studies addressing the Uphold. She also contends that Dr. Culligan may not reliably base his Uphold opinions on studies about other POP products because Dr. Culligan testified that he did not have detailed knowledge as to how these products compare. He additionally testified that there are no direct comparison studies concerning these products. *See* Culligan Dep. 301:14–302:9, Jan. 12, 2015 [ECF No. 38-3]. Even so, I find Dr. Culligan's method to be reliable. As revealed by his expert report and his relied-upon list, Dr. Culligan based his opinions on scientific literature, including a published study that he conducted on the Uphold. *See* Culligan Report Ex. B [ECF No. 38-2]. If the plaintiff wishes to argue that his conclusions are not correct in light of his research, then she may do so on cross-examination.

Next, the plaintiff challenges Dr. Culligan's opinion that the Uphold is safer and more effective than traditional non-mesh POP procedures.[20] *Id.* at 18. The plaintiff states that Dr. Culligan "admitted . . . [t]here are no studies that compare the safety of the Uphold device to the safety of non-mesh surgeries . . . [and] [t]here are no studies that compare the efficacy of the Uphold device to the efficacy of non-

[20] BSC contends in its response that the plaintiff does not challenge this opinion. Upon my reading of the plaintiff's motion, I disagree.

mesh surgeries."Mot. re: Culligan 3–4 [ECF No. 38]. The deposition testimony that the plaintiff cites in support of this proposition is as follows:

> **Q:** Okay. Are there any RCTs comparing native tissue repairs to Uphold for safety?
>
> **A:** There are no studies of any sort I'm aware of where an outcome has recalled safety is [sic] one of the outcome measures. I think that that's a very broad topic, and -- and you couldn't design a study around, quote-unquote, safety as an outcome measure.
>
> . . . .
>
> **Q:** . . . . Are there any long-term RCTs that exist comparing native tissue repair to Uphold for efficacy?
>
> **A:** No.

Culligan Dep. 294:4–13, 294:18–22, Jan. 12, 2015. However, Dr. Culligan's method is not unreliable just because a direct comparison study does not exist between these treatments.

The plaintiff's remaining arguments concerning the reliability of Dr. Culligan's safety and efficacy opinions are also unavailing. First, the plaintiff argues that Dr. Culligan may not reliably consider his personal experience in forming his opinions because Dr. Culligan could not testify as to exact statistics about his patients (i.e., how many patients he has implanted with an Uphold). However, such detail is not required under *Daubert* to opine as to the "*large-scale* safety and efficacy of the Uphold device," as the plaintiff phrases it. Mot. re: Culligan 4 (emphasis added).[21]

[21] At this point in her motion, the plaintiff also challenges an opinion that Dr. Culligan asserts at his deposition—that the complication rate in his patients implanted with the Uphold is one percent. Dr. Culligan testifies that he would not provide the basis for this opinion to the plaintiffs' lawyers without first requesting legal advice on the matter. *See* Culligan Dep. 249:1–18, Jan. 12, 2015. However, this opinion is not within Dr. Culligan's report. Culligan Report 18–19. Thus, I must presume that Dr.

Second, the plaintiff argues that Dr. Culligan failed to account for contrary literature in forming his opinions about the safety and efficacy of the Uphold. The plaintiff merely cites to the following deposition testimony in support:

> **Q:** Dr. Culligan, if Boston Scientific said internally that mesh shrinks, do you disagree with that?
>
> **A:** I've already disagreed with it. I think many people believe that. But I think that it's not been proven, and I simply choose not to believe it. I think it's a bit of a myth.

Culligan Dep. 388:21–389:7, Jan. 12, 2015 (objection omitted). I am satisfied that Dr. Culligan followed a reliable methodology in reaching his opinions on the safety and efficacy of the Uphold device, notwithstanding the plaintiff's citation to the above deposition testimony. Furthermore, I decline to address Dr. Culligan's opinion on shrinkage here. The plaintiff brings a separate challenge to such opinions, which is addressed below. Thus, the plaintiff's motion with respect to this matter is **DENIED**.

2. Physical Properties of Polypropylene Mesh

Next, the plaintiffs challenge the reliability of Dr. Culligan's opinion on the physical properties of mesh, including the nonoccurrence of shrinkage, foreign body response, and degradation. Dr. Culligan claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon peer-reviewed literature.

The advisory committee notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and

Culligan does not plan to offer it at trial, and I need not assess the reliability of it.

> how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g., Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty").

On the one hand, Dr. Culligan has based his opinions on his extensive clinical experience and a review of the medical and scientific literature, which, in the abstract, are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished

from experience examining mesh explants. Perhaps Dr. Culligan did not observe evidence of mesh contraction because he was not looking. Or perhaps his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical community or medical literature can be difficult to assess. Although the expert report indicates Dr. Culligan reviewed an extensive list of literature in forming his opinions generally, the court is directed to minimal specific support for the statements at issue or detail about Dr. Culligan's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

3. DFU

The plaintiff also argues that Dr. Culligan is unqualified to opine as to the Uphold DFU. *See* Culligan Report 18. I agree. Dr. Culligan has participated in drafting a DFU yet hired a regulatory consultant to assist him and check his work. *See* Culligan Dep. 383:7–16, Jan. 12, 2015. In prior cases, he testified as to his lack of expertise in this area. *See Tyree*, 54 F. Supp. 3d at 582. Just because Dr. Culligan now states that he has not given himself enough credit as to his qualifications in the past—specifically, that he was "literally just being too hard on [him]self"—is not sufficient for the court to deem him qualified to opine as to this matter. Culligan Dep.

82:20–21, Jan. 12, 2015. BSC has not "come forward with evidence from which the court" can find Dr. Culligan qualified here. *Md. Cas. Co.*, 137 F.3d at 783. His opinions on the DFU are **EXCLUDED**.

4. **MSDS**

The plaintiff next challenges Dr. Culligan's opinions concerning the MSDS. BSC concedes that Dr. Culligan will not offer opinions "regarding the meaning of statements contained in the Phillips Sumika Material Safety Data Sheet." Resp. re: Culligan 4 n.12 [ECF No. 66]. Also, I decline to entertain the plaintiff's challenge to Dr. Culligan's other opinions concerning the MSDS. At Dr. Culligan's deposition, the parties agreed as to the parameters of his testimony on this matter. The parties agreed that Dr. Culligan could testify that "[he] didn't know what an MSDS sheet was and that 'he'd never consulted one." Culligan Dep. 171:19–23, Jan. 12, 2015. The plaintiff's counsel questioned Dr. Culligan as follows:

> **Q:** Okay. So what you're going to say about the MSDS is that had, before reading the plaintiffs' experts' opinions, you—you didn't know what an MSDS sheet was and that you've never consulted one. Are those the only two real opinions you're going to give on the MSDS sheet?
>
> **A:** Sure. . . .
>
> **Q:** Okay. Yeah. I mean, if we can agree those are the only two things that you're going to say is that you've—you didn't know what one was before this litigation and that you never consulted one, then I can move on. . . .
>
> **A:** I see.
>
> **Q:** But if we can agree to that, then we're good?
>
> **A:** Okay. We're good.

Q: So we can agree to that?

A: Yes, we can.

Q: Okay.

Id. at 171:16–172:23. Thus, the plaintiff's challenge is moot. The plaintiff's motion with respect to Dr. Culligan's MSDS opinions is **DENIED as moot**.

5. Patient Brochure

Although the plaintiff argues that Dr. Culligan's opinions on any patient brochures should be excluded, BSC concedes he will not offer such opinions at trial. Resp. re: Culligan 4 n.12. Thus, the motion with respect to this matter is **DENIED as moot.**

6. Opinions on FDA

Although the plaintiff argues that Dr. Culligan's opinions concerning the FDA should be excluded, BSC concedes he will not offer such opinions at trial. *Id.* Thus, the motion with respect to these opinions is **DENIED as moot**.

In sum, the plaintiff's Motion to Exclude Certain Opinions and Testimony of Dr. Patrick Culligan [ECF No. 38] is **GRANTED in part**, **DENIED in part,** and **RESERVED in part**.

C. Christine Brauer, Ph.D.

The plaintiff seeks to exclude the expert opinions of Christine Brauer, Ph.D. Dr. Brauer is the President of Brauer Device Consultants LLC, where she provides consulting services to the medical device industry regarding FDA regulatory requirements. The plaintiff seeks to exclude both of Dr. Brauer's expert reports filed

on November 21, 2014. The first report ("FDA report") focuses on the FDA regulatory framework for surgical devices, and the second report ("supplemental report") focuses on industry standards that a manufacturer of a medical device must meet. *See* Brauer Dep. 8:11–23, Jan. 8, 2015 [ECF No. 48-5]. "Anticipating that the Court will adopt its prior rulings and exclude FDA evidence here," BSC does not contest the plaintiff's motion with regard to the FDA report. Resp. re: Brauer 1 [ECF No. 68]. In *Sanchez*, I ruled as follows:

> I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. This is consistent with prior rulings by this court. Accordingly, I **FIND** that Dr. Brauer's opinions should be excluded in their entirety.

Sanchez, 2014 WL 4851989, at *36–37 (citations omitted). Accordingly, the plaintiff's motion with regard to Dr. Brauer's FDA report is **GRANTED**, and her opinions set forth in that report are **EXCLUDED**.

With regard to the supplemental report, the plaintiff contends that it "is nothing more that [sic] her FDA Report under a different cloak." Reply re: Brauer 4 [ECF No. 87]. Therefore, in the plaintiff's view, Dr. Brauer's supplemental report should be excluded for the same reasons her FDA report was previously excluded, given that the two reports are "substantially identical." Am. Mot. re: Brauer 2 [ECF No. 48]. I agree. Reading the two reports side by side, it appears that Dr. Brauer "supplemented" her report by removing references to the FDA and substituting the term "industry standard" instead. For example, in her supplemental report, Dr.

Brauer states: "It is an industry standard for a manufacturer of certain new or modified medical devices to demonstrate that its new device is substantially equivalent to another legally marketed device, and is as safe and effective as other similar devices prior to marketing in this U.S." Brauer Report 4, Nov. 21, 2014 [ECF No. 48-4]. This "industry standard" clearly describes the FDA 510(k) process, which Dr. Brauer admits in her deposition. *See* Brauer Dep. 43:3–14, Jan. 8, 2014 [ECF No. 48-5] ("Q: I'm talking about this one sentence . . . That's the 510(k) process; correct? / A: That is the 510(k) process.").

Also, Dr. Brauer states that medical devices are grouped into three categories, which she labels as "Low-Risk," "Moderate Complexity and Risk," and "Complex, High Risk." These "industry standard" categories perfectly align with the three regulatory classes established by the Medical Device Amendments, another fact Dr. Brauer admits. *See id.* at 48:1–12 ("Q: The low-risk medical devices are Class I devices. The moderate complexity and risk medical devices are Class II devices; correct? A: For most products, they probably would fit in that way, yes.").

BSC contends that Dr. Brauer's industry standard opinions do not require presenting FDA evidence to the jury because the industry standards are broader than FDA regulations. However, Dr. Brauer explains that FDA regulations are part of industry standards, and therefore, any evidence with regard to industry standards would require reference to the FDA, whether it is disguised or not. *See id.* at 34:10-19 ("A: When you do it with industry, you want to make sure that your regulatory requirements are met, but also that certain customer needs are met. So there's a little

different of a slant, but it's still the primary same content. Q: So in both ways you're trying to comply with FDA regulations? A: In part. In both ways you're trying to comply with FDA regulations because that's part of it.").

Furthermore, although she cites a few standards issued by the International Organization for Standardization ("ISO"), including ISO 13485, in her supplemental report, when asked about additional standards during her deposition, Dr. Brauer cannot recall any specific standards, other than ISO 13485. *Id.* at 35:3–17. And when pressed on whether there is an ISO standard that requires manufacturers to submit adverse events to the FDA, Dr. Brauer is unable to articulate an identifiable ISO standard to support her premise. *See id.* at 46:13–20 ("Q: It says that it's an industry standard to submit certain reports to adverse events to the FDA. A: That's correct. Q: So there's no actual standard that says that; correct? A: I don't believe it's that specifically stated in the ISO standard."). Dr. Brauer's inability to identify an applicable standard renders her opinion unreliable. *See Lasorsa v. Showboard: The Mardi Gras Casino*, No. 07-4321, 2009 WL 2929234, at *5 (D.N.J. Sept. 9, 2009) ("Without a reliable, objective basis for [expert] testimony, stemming from identifiable industry standards, codes, publications or training, it must be precluded under Rule 702.").

Dr. Brauer's deposition testimony reveals that her true area of expertise is the regulatory field, which is why she was originally retained to write a regulatory report. *See* Brauer Dep. 12, Jan 12, 2015 ("I believe the first contact was regarding FDA regulation of medical devices."); *see also Pension Comm. of Univ. of Montreal Pension*

Plan v. Banc of Am. Sec., LLC, 691 F. Supp. 2d 448, 476 (S.D.N.Y. 2010) (finding an expert's opinions with regard to industry standards unreliable when not "ground[ed] in his knowledge of the custom and practice of the industry"). There is far too much overlap between Dr. Brauer's FDA report and supplemental report to avoid a regulatory mini-trial, which I have repeatedly and consistently held would confuse and mislead the jury. Accordingly, the plaintiff's Amended Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 48] is **GRANTED**, and Dr. Brauer's opinions are **EXCLUDED** in their entirety. The plaintiff's initial Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 37] is **DENIED as moot**.

D. Roger Goldberg, M.D.

The plaintiff seeks to exclude the opinions and testimony of Roger Goldberg, M.D. Dr. Goldberg is the Director of the Division of Urogynecology at NorthShore University HealthSystem and an Associate Professor of Obstetrics and Gynecology at the University of Chicago Pritzker School of Medicine. Goldberg Report 1 [ECF No. 35-2]. He is a member of the board of directors for AUGS and is the co-inventor of the Uphold. *Id.* The plaintiff argues that Dr. Goldberg's opinions should be excluded because "they violate the standards for independence of study or publication within his area of science" and because they are "based purely on his personal experience." Mot. re: Goldberg 3–4 [ECF No. 35]. The plaintiff also raises qualifications and reliability challenges to Dr. Goldberg's proffered testimony.

1. Conflict of Interest

First, the plaintiff argues that Dr. Goldberg is biased in favor of the Uphold because he invented it and because he testified that he has been paid approximately $1.4 million from BSC since 2005. *See* Goldberg Dep. 304:13–21, Dec. 13, 2013 [ECF No. 35-3]. She argues that Dr. Goldberg has recused himself from participating in Uphold studies to avoid any perceived bias and that, as a result, his interest in the Uphold should also exclude his testimony here. I find such an argument unavailing under *Daubert*. Bias and witness credibility are appropriate topics for cross-examination. The plaintiff's motion with respect to this matter is **DENIED**.

2. Personal Experience

Next, the plaintiff argues that Dr. Goldberg's opinions on the Uphold's safety should be excluded as unreliable because they are based solely on his personal experience. In particular, the plaintiff quotes ten of Dr. Goldberg's opinions. I disagree and decline to exclude *all* of Dr. Goldberg's safety opinions based on this argument—specifically because *Daubert* permits an expert to rely heavily on his experience to form opinions. Dr. Goldberg's relied-upon list plainly reveals that he also considered scientific literature in forming his opinions. Goldberg Report Ex. B [ECF No. 35-2]. Dr. Goldberg states this fact in his expert report. *Id.* at 2 (stating that his opinions "are based on [his] education, training, clinical experience, *and* review of medical and scientific literature" (emphasis added)). Thus, even if Dr. Goldberg testified or wrote that he based an opinion on personal experience, his attached relied-upon list cannot be ignored. *Id.* at 20. Moreover, some of the same opinions quoted and challenged in this section of the plaintiff's brief are also challenged in a

more specific manner later in her brief. I will address those challenges below. Otherwise, I decline to impose a blanket exclusion on all of Dr. Goldberg's safety opinions on the reasoning that they are based on his personal experience. The plaintiff's motion with respect to this matter is **DENIED**.

3. Complication Rate

The plaintiff argues that Dr. Goldberg's opinion that the complication rate for the Uphold is less than 3 percent should be excluded because it is based on a calculation of cases at his medical center and is not supported by any scientific studies. However, BSC claims that "Dr. Goldberg's *data was published by a peer-reviewed journal*" and attaches the study in support. BSC's Resp. re: Goldberg 9 [ECF No. 63]; *see also* Manhan K. Vu et al., *Minimal Mesh Repair for Apical and Anterior Prolapse: Initial Anatomical and Subjective Outcomes*, 23 Int. Urogynecol. J. 1753, 1753–61 (2012) [ECF No. 63-3].

The plaintiff makes several arguments in her reply as to why this opinion is still unreliable. For example, she argues that "only a subset of the data was included" in the Vu study and that approximately 40 percent of all of the data from his center has not been published yet. Reply re: Goldberg 3–4 [ECF No. 86]. However, these arguments are without merit. Under *Daubert*, I need not decide whether a peer-reviewed article is accurate. Such questions are appropriately addressed on cross-examination. This aspect of the plaintiff's motion is **DENIED**.

4. Physical Properties of Polypropylene

First, the plaintiffs challenge Dr. Goldberg's qualification to opine on the

physical properties of mesh because he is not a materials scientist, biomedical engineer, or a pathologist and admits as much. However, his extensive clinical experience surgically treating pelvic floor disorders with mesh, as well as his review of and contributions to the medical and scientific literature adequately qualify him to opine on polypropylene. Accordingly, BSC's motion as to Dr. Goldberg's qualifications is **DENIED**.

Next, the plaintiffs challenge the reliability of Dr. Goldberg's opinion on the physical properties of mesh—specifically that the device in question does not degrade, contract, or encapsulate. Dr. Goldberg claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon relevant medical and scientific literature. On the one hand, these are reasonable bases from which to form an expert opinion. On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations or the methodology. Further, I have no basis to assess claims that Dr. Goldberg's observations are supported by the scientific community.

For the reasons discussed at length in my analysis of Dr. Culligan, I am without sufficient information at this time to determine the reliability of Dr. Goldberg's opinions on the physical properties of mesh. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

5. Response to Plaintiff's Experts' Claims

Lastly, the plaintiff argues that all of Dr. Goldberg's opinions in response to the plaintiff's experts' claims should be excluded because he is not qualified and his

method was unreliable. Specifically, the plaintiff objects to Dr. Goldberg's opinions on (1) vaginal mesh implantation, (2) the MSDS, and (3) the severity of complications in the DFU.

a. Vaginal Mesh Implantation

The plaintiffs challenge the reliability of Dr. Goldberg's opinion stating that the plaintiff's experts are wrong that bacteria in the vagina make transvaginal mesh surgery inadvisable—specifically that polypropylene does not become routinely infected. Dr. Goldberg claims he based this opinion on his clinical experience, during which he did not encounter mesh infection, and upon peer-reviewed literature. This opinion presents the same challenges to assessing reliability as those discussed above. For the reasons discussed in my analysis of Dr. Goldberg's and Dr. Culligan's opinions on the physical properties of polypropylene, I am without sufficient information at this time to determine the reliability of Dr. Goldberg's opinions on mesh infection. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

b. MSDS

The plaintiff argues that Dr. Goldberg is unqualified to opine as to the MSDS for polypropylene mesh. In his report, he states:

> I have never used an MSDS in making clinical decisions, or in counseling patients on the risks or benefits of any medical treatment. Nor have I ever heard of any other surgeon using an MSDS in this manner. I have also seen no evidence that the MSDS to which Plaintiffs' experts refer is based on any medical or scientific evidence that raises any valid safety concern about the mesh used in the Uphold, or any other Boston Scientific Product.

Goldberg Report 23–24. These are not expert opinions. Thus, I need not address them under *Daubert*. The plaintiff's motion with respect to this matter is **DENIED**.

c. DFU

Dr. Goldberg opines that "[s]urgeons are well aware of the clinical implications of complications such as infection, pain, erosion, and dyspareunia, including the potential for the complications to be serious or permanent, and the DFU provided an appropriate level of detail and scope of information." *Id.* at 24–25. However, Dr. Goldberg does not provide the court with the basis for this opinion, so the court cannot conclude that it is the result of a reliable methodology. Thus, Dr. Goldberg's opinion is **EXCLUDED** as unreliable. *See Daubert*, 509 U.S. at 590 ("Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds' based on what is known.").

Accordingly, as set forth above, the plaintiff's Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. [ECF No. 35] is **GRANTED in part** and **DENIED in part**.

E. Stephen Spiegelberg, Ph.D.

The plaintiff seeks to exclude the expert opinions of Stephen Spiegelberg, Ph.D. Dr. Spiegelberg is the president and co-founder of Cambridge Polymer Group Inc., where he directs a team of scientists who perform contract research, analytical testing, and device development for the biomedical and polymer communities. Broadly, Dr. Spiegelberg opines that BSC's pelvic mesh products "are appropriate for their intended use in design and manufacture." Spiegelberg Report 4 [ECF No. 53-2].

The plaintiff objects to the following general causation opinions offered by Dr. Spiegelberg: (1) general causation opinions regarding the position statements of medical organizations; (2) any matters related to the FDA clearance process; (3) opinions regarding the presence of black specks in BSC's mesh; and (4) opinions based on Fourier Transform Infrared Spectroscopy ("FTIR") and Energy Dispersive Spectrometry ("EDS"). I address these objections in turn.

1. **Position Statements**

First, the plaintiff argues that Dr. Spiegelberg's opinions regarding position statements should be excluded because (1) they are not contained in his expert report; (2) he is not qualified to offer such opinions; and (3) he lacks any reliable methodology. In response, BSC states that Dr. Spiegelberg does not offer opinions regarding position statements in either his expert report or his most recent deposition. Upon review, I agree with BSC that Dr. Spiegelberg does not in fact offer the opinions the plaintiff seeks to exclude. Accordingly, the plaintiff's motion with regard to position statements is **DENIED as moot**.

2. **FDA**

Next, the plaintiff contends that Dr. Spiegelberg is unqualified to opine on the FDA 510(k) clearance process and that such opinions should be excluded as irrelevant. In response, BSC concedes that Dr. Spiegelberg will not offer opinions on the FDA 510(k) clearance process. Accordingly, the plaintiff's motion with regard to the FDA is **DENIED as moot.** .

BSC limits its concession by arguing that Dr. Spiegelberg is qualified to opine on ISO standards based on his "extensive experience in the field of medical device

analysis and design." Resp. re: Spiegelberg 6 [ECF No. 81]. I agree. Dr. Spiegelberg's current work revolves around medical device development and consultation. *See* Spiegelberg Report 2. He is also the Task Force Chairman for ASTM standards involving the cleanliness of biomedical devices and characterization methods for polymers. *Id.* at 3. Consulting on the development of new medical products requires familiarity with the applicable industry standards. Therefore, to the extent Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so. Accordingly, the plaintiff's motion with regard to Dr. Spiegelberg's qualifications is **DENIED**.

3. Black Specks or Spots

Next, the plaintiff argues that Dr. Spiegelberg's opinions regarding black specks in BSC's mesh are unfounded and unreliable. In his expert report, Dr. Spiegelberg states: "I have reviewed information suggesting 'black spots' may appear in the polypropylene. These 'black spots' are actually reflections of light on the curves of the mesh when pictures are taken, rather than inclusions or defects in the mesh." Spiegelberg Report 12. Dr. Spiegelberg elaborated on this conclusion in his deposition:

> **Q:** And if I remember—do you remember what your opinion was in regard to black specks?
>
> **A:** I do.
>
> **Q:** Can you tell me?
>
> **A:** The black specks that I observed in the meshes were not black specks per se, as in terms of inclusions, rather were just reflections that are often inherent in circular surfaces.

Q: And did you perform independent testing to verify that?

A: Yes, I did.

Q: And could you describe that to me?

A: You take the mesh and place it in an optical microscope, and then rotate the mesh under the optical microscope and see if the black specks move or disappear, which they did.

Spiegelberg Dep. 17:22–18:14, Jan. 14, 2015 [ECF No. 81-1]. The plaintiff contends that Dr. Spiegelberg's findings are unreliable because he did not review the photographs supplied by the plaintiff's expert, Dr. Dunn, nor did he take his own photographs. However, in his deposition, Dr. Spiegelberg testified that he did review Dr. Dunn's photographs. *Id.* at 19:15. Whether Dr. Spiegelberg took his own photographs does not sufficiently undermine the reliability of his analysis here. Challenges to Dr. Spiegelberg's ultimate conclusion with regard to the nature of the black spots are better suited for cross-examination. Accordingly, the plaintiff's motion with regard to black specks or spots is **DENIED**.

4. FTIR and EDS

Last, the plaintiff seeks to limit Dr. Spiegelberg's general causation opinions based on his FTIR and EDS testing. However, the plaintiff also states that Dr. Spiegelberg's "admissions regarding the limitations of these techniques may also be grounds for cross-examination" and thus seeks only "qualification or explanation of the limitations inherent to these techniques" in order to avoid misleading or confusing the jury. Mot. re: Spiegelberg 11 [ECF No. 53]. The plaintiff will have the opportunity to adequately highlight these limitations at trial upon cross-examination. Accordingly, the plaintiff's motion with regard to Dr. Spiegelberg's FTIR and EDS

testing is **DENIED**.

In sum, the plaintiff's Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 53] is **GRANTED in part** and **DENIED in part**.

F. Stephen F. Badylak, D.V.M., Ph.D., M.D.

The plaintiff seeks to exclude the expert opinions of Stephen F. Badylak, D.V.M., Ph.D., M.D. Dr. Badylak is the Deputy Director of the McGowan Institute for Regenerative Medicine, Director of the Center for Preclinical Studies, and a tenured professor with the Department of Surgery at the University of Pittsburgh. Broadly, Dr. Badylak opines that the polypropylene mesh used in BSC's pelvic mesh products is biocompatible and safe for use in the human body. The plaintiff asks the court to exclude Dr. Badylak's (1) opinions related to the risk/benefit analysis or the safety and efficacy of BSC devices; and (2) opinions related to oxidative degradation.

1. Risk-Benefit Analysis or Safety and Efficacy

First, the plaintiff contends that Dr. Badylak should be precluded from opining on the safety and efficacy of polypropylene mesh devices because he has not reviewed the applicable scientific literature and he has no clinical experience using these devices. In support of her argument regarding scientific literature, the plaintiff cites to a portion of Dr. Badylak's deposition where he "admitted" that he has not performed a "comprehensive review" of the literature related to specific BSC devices. Mot. re: Badylak 7 [ECF No. 54]. However, Dr. Badylak's expert report indicates that he reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices. Resp. re: Badylak 8 [ECF No. 65]; *see also* Badylak Report Ex. B [ECF No. 54-2]. Furthermore,

Dr. Badylak explains that he is more familiar with the body of literature reviewing the safety and efficacy of surgical mesh generally, versus literature specific to any one device. *See* Badylak Dep. 98:22–25, Jan. 14, 2014 [ECF No. 54-5]; *see also Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100 (10th Cir. 1991) (explaining that "a lack of specialization does not affect the admissibility of the opinion, but only its weight"). This explanation does not undermine his qualifications but instead clarifies his approach. If there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination.

Similarly, the plaintiff's arguments regarding Dr. Badylak's clinical experience are also without merit. Dr. Badylak has extensive experience in the field of biomaterials, including the design of implantable surgical mesh devices. *See* Badylak Report 1. The qualification requirement of Rule 702 does not necessarily require specific clinical experience implanting the device at issue. *See Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989) ("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion."); *see also Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *4–5 (S.D. W. Va. July 8, 2014) (finding expert qualified to offer general causation opinions despite his lack of specific experience with the product at issue). Accordingly, the plaintiff's motion with regard to Dr. Badylak's safety and efficacy opinions is **DENIED**.

2. Degradation

Lastly, the plaintiff argues that Dr. Badylak's opinions with regard to oxidative

degradation based on the scientific literature are unreliable because he contradicted himself during his deposition by acknowledging the "phenomenon" of oxidative reactions. *See* Badylak Dep. 122:2–6 [ECF No. 53-5] ("I'm aware of the literature and the discussion, I'm aware of phenomenon of oxidative changes and oxidative reactions in the body everywhere, including the surface of biomaterials such as polypropylene, so yes, I've considered that. . . . As a matter of fact, I'm on record as saying oxidative reactions occur everywhere, including the surface of biomaterials."). However, the plaintiff omits Dr. Badylak's subsequent testimony, where he states: "What I don't believe is that these oxidative reactions at the surface of polypropylene are resulting in the degradation that's causing further problems. There's no evidence to suggest that exists." *Id.* at 122:11–15. Upon review of the deposition, I do not find Dr. Badylak's testimony sufficiently contradictory to undermine the reliability of his expert opinions. Accordingly, the plaintiff's motion with regard to degradation is **DENIED**.

The plaintiff's Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 54] is thus **DENIED**.

G. Michael L. Douso, M.D.

The plaintiff seeks to exclude the expert opinions of Michael L. Douso, M.D. Dr. Douso is a urogynecologist practicing in Florida. He specializes in minimally invasive gynecologic surgery and urogynecology. He has extensive experience treating women with SUI and POP. Douso Report 1 [ECF No. 29-1]. The plaintiff seeks to have the following opinions of Dr. Douso excluded: (1) opinions regarding the

efficacy of the Prefyx; (2) opinions related to non-prepubic mid-urethral sling data and position statements; (3) opinions regarding the adequacy of the Uphold and Prefyx DFUs; and (4) opinions regarding the physical properties of the Uphold and Prefyx.

1. Prefyx Efficacy

The plaintiff argues that Dr. Douso's opinions regarding the efficacy of the Prefyx are "simply unreliable." Mot. re: Douso 3 [ECF No. 29]. The plaintiff avers that because Dr. Douso did not review or rely on peer-reviewed scientific literature in forming his efficacy opinions, Dr. Douso's testimony regarding Prefyx efficacy should be excluded. The plaintiff also asserts that Dr. Douso has "abandoned" his efficacy opinions. *Id.* at 6.

In his deposition, Dr. Douso acknowledged that he did not rely on peer-reviewed clinical studies regarding the efficacy of prepubic slings: "I do not rely on a clinical study because there are no clinical studies to rely upon, per se." Douso Dep. 104:23–25, Jan. 6, 2015 [ECF No. 64-2]. The plaintiff, however, concedes in her filings that there is an utter dearth of studies related to the Prefyx. The plaintiff points out that only two studies of the Prefyx exist: one is the Dr. Lind study, and the other is an internal BSC study. Mot. re: Douso 4–5; Reply re: Douso 3 [ECF No. 67] ("The only other study that exists related to Prefyx effectiveness is an internal BSC study that Dr. Douso never reviewed prior to forming his opinions on Prefyx effectiveness."). The plaintiff states that during Dr. Douso's deposition, "Plaintiff's counsel . . . provided Dr. Douso with the results of the only other study related to the Prefyx device, which

Defendant failed to provide him." Mot. re: Douso 4.

As for the Lind study, the only other study regarding the Prefyx, the plaintiff's counsel pointed out in Dr. Douso's deposition the following: "Would you agree with me that the primary author of this study said that . . . the study publication would not be feasible or scientifically valid due to potential invalid results and poor study design would make that study a bad study to rely upon?" Douso Dep. 111:10–14, Jan. 6, 2015. Dr. Douso stated, "Yes, I would have to agree with that." *Id.* at 111:17. Dr. Douso goes on to state that he would not remove the references to the Lind study in his expert report. *Id.* 111:18–112:4. Dr. Douso explained that the Lind study was but one data point in his opinion, and there is not "absolute fulcrum" to his opinion. *Id.* at 105:12–13. Dr. Douso goes on to state the following:

> I would agree that the effectiveness of the product was far less than was hoped for. That's for sure. However, in my own hands . . . the product was somewhat more effective than it was in the Lind study over time. But I also voluntarily discontinued the use of the prepubic sling simply because, yes, its effectiveness was less than the other products I could have chosen. But that's yet another data point.

Id. 118:7–14.

In essence, Dr. Douso relied upon one study regarding the Prefyx, whose own author discounted it as unreliable. Further, Dr. Douso relies on his own experience to state that the Prefyx was more effective over time in his "own hands," but he ultimately discontinued use of the device due to its lack of efficacy. Dr. Douso's opinion on this matter is unreliable, and it is **EXCLUDED**.

2. Non-Prepubic Mid-Urethral Sling Data and Position Statements

The plaintiff next argues Dr. Douso should not be permitted to discuss the long-

term data or position statements from various medical organizations that support his opinion that mid-urethral slings constructed of Type 1 polypropylene mesh are recognized as the gold standard in treating SUI. Specifically, the plaintiff states that "the data and the position statements are irrelevant and not a proper fit for this case as they are not related to the Prefyx prepubic sling." Mot. re: Douso 6. The plaintiff goes on to state that "[a]ll the data to which Dr. Douso cites within his report relate to other types of slings (*i.e.*, retropubic, transobtorator, and single incision). None of the data relates to prepubic slings . . . ." *Id.* at 7.

In his expert report, Dr. Douso cites to several position statements issued by various medical organizations, and Dr. Douso states that he concurs "with the views set out in each of these position statements and believe[s] that mid-urethral slings constructed of Type 1 polypropylene mesh represent the 'gold standard' in treating women with SUI." Douso Report 5. Dr. Douso states, "Ms. Trevino was implanted with a Prefyx sling on December 28, 2009. At the time of Ms. Trevino's surgery, long-term data already existed supporting the use of mid-urethral slings constructed of Type 1 polypropylene mesh in pelvic floor repair, and [the data] was well known in the gynecologic community." *Id.* at 8. Dr. Douso has extensive experience with treating patients with the Prefyx sling, and the Prefyx sling was made from the same Type 1 polypropylene. *Id.* at 4, 12 ("Boston Scientific's mesh devices are all constructed from the same Type 1 polypropylene mesh material.").

Dr. Douso states the following in his deposition:

A. There was an awful lot of data quoted here in my opinion. The Prefyx was not qualitatively different in its properties than any

of the existing mesh slings.

Q. Let me stop you there. So my question is when you're saying this, when you're making these comments about long-term data related to mid-urethral slings, your emphasis is on the polypropylene. It's not on the type of sling, meaning whether it was transobturator, retropubic, or prepubic.

A. No, it has nothing to do with the approach. The material has long been used before Prefyx was developed.

Q. So my question being, though, is there . . . no long-term data that you have that you can show me regarding prepubic slings?

A. No, I cannot. However, I can show you lots of data about similar products placed obviously through a different anatomic setting, which very interestingly in this particular case was not placed prepubicly at all.

Douso Dep. 99:3–22, Jan. 6, 2015.

Despite the lack of peer-reviewed literature in the scientific community regarding prepubic slings generally and the Prefyx specifically, Dr. Douso quoted a substantial amount of data in his report focusing on properties of other existing mesh slings that, according to Dr. Douso, were not qualitatively different from the Prefyx. *See* Douso Report; Douso Dep. 99:3–6, Jan. 6, 2015. Dr. Douso says, "[M]y opinions come from long experience, they come from the medical literature in general, and they come from a variety of sources. You know, lest we forget, I had a great deal of experience with [Prefyx]." Douso Dep. 102: 10–13, Jan. 6, 2015. Dr. Douso's opinions regarding the long-term data of the alleged success of other mesh slings derive from the fact that the Prefyx and other BSC mesh slings were all made from the same material: Type 1 polypropylene. Dr. Douso suggests the approach of implantation of the device is not important, particularly because Mrs. Trevino was implanted with

the Prefyx, but her device was not implanted prepubicly. *Id.* 99:19–22 ("However, I can show you lots of data about a similar product placed obviously through a different anatomic setting, which very interestingly in this particular case was not placed prepubicly at all.").

The plaintiff does not challenge Dr. Douso's method of comparing devices that are made of the same materials; the plaintiff simply argues the data Dr. Douso relies upon is not relevant because the data was not collected specifically regarding prepubic slings. The plaintiff makes no argument that the approach used in implantation has any bearing on the overall success of the device. Accordingly, the plaintiff's motion is **DENIED** on this point.

3. Adequacy of DFUs

The plaintiff next argues Dr. Douso should be excluded from offering opinions regarding the adequacy of the DFUs for both the Prefyx and the Uphold. The plaintiff argues Dr. Douso is unqualified to offer the following opinions: (1) the Uphold and Prefyx "adequately warn of all potential mesh risks" and that these risks "are not new;" (2) added complications rates to the Uphold and Prefyx DFUs would be "inappropriate;" and (3) instruction on mesh removal in the DFUs is not necessary for an adequate warning. Mot. re: Douso 8. According to the plaintiff, "Nothing within Dr. Douso's curriculum vitae indicates that he possesses enough knowledge, skill, experience, training, or education to allow him to offer Rule 26 witness opinions on the adequacy of the Uphold and Prefyx DFUs." *Id.* at 9. The plaintiff points out the following exchange from Dr. Douso's deposition:

> **Q.** You don't have any background in product label warnings; right?
>
> **A.** No, sir.
>
> **Q.** Okay. You don't have any training in product label warnings; right?
>
> **A.** No, sir.
>
> **Q.** You don't have any FDA training, do you?
>
> **A.** No, sir.

Douso Dep. 86–87, Jan. 6, 2015 [ECF No. 29-2].

The defendant counters the plaintiff's arguments by stating as follows:

> First, Dr. Douso intends to offer a clinician's perspective that the DFUs provide accurate statements of the risks and complications he has encountered in his practice and his review of medical literature, and that these DFUs disclose the alleged complications of which Ms. Trevino complains. Second—and only if Plaintiff's witnesses offer specific criticisms of the DFUs that contradict norms within Dr. Douso's clinical specialty—he will explain that these specific contentions are inconsistent with clinical experience.

Resp. re: Douso 7. The defendant goes on to state that "Dr. Douso's opinion here is not that there are no risks other than those he has personally observed in his practice; rather, it is that the risks complained of by Plaintiff, and described by Plaintiff's experts, are known in the medical community and adequately warned of in the DFUs." *Id.* at 10.

Dr. Douso's expert report directly contradicts the defendant's brief; Dr. Douso offers broader opinions than the defendant would have the court believe. First, Dr. Douso does identify various risks and complications that are listed on the DFUs, and he concludes that all of the risks and complications identified in his report "are

adequately warned of in the [DFUs] for the Prefyx and Uphold products." Douso Report 9. This opinion, of course, is based solely upon Dr. Douso's clinical experience. Dr. Douso goes on to state the following: "The DFU that accompan[ies] the Uphold adequately warms of *all potential mesh risks*, including erosion and those identified [in the report]. . . . The same risks exist for mid-urethral slings like the Prefyx. As is the case with the Uphold, the Prefyx DFU adequately warns of these risks." *Id.* (emphasis added).

Dr. Douso's expert opinions clearly attempt to encompass all possible risks in his assessment of the adequacy of the DFUs. I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urogynecologist, is not qualified to opine that a product warning was adequate merely because it included the risks he has observed in his own practice. *See Tyree*, 2014 WL 5486694, at *70. As Dr. Douso has testified, he has no experience or training relating to product warnings and labels. Douso Dep. 86–87, Jan. 6, 2015. Accordingly, I **FIND** that Dr. Douso is not qualified to opine on the adequacy of product warnings, and therefore, his opinions related to the DFUs for the Uphold and Prefyx are **EXCLUDED**.

4. Physical Properties of the Uphold and Prefyx

The plaintiff next argues that Dr. Douso is unqualified to offer opinions regarding the physical properties of the Uphold and Prefyx devices and that his opinions are unreliable.

As to qualification, the plaintiff states "Dr. Douso is not . . . qualified to offer opinions on this topic as well because he is not an engineer, biomechanist, chemist,

polymer scientist, and has never tested the products." *Id.* Dr. Douso is a practicing urogynecologist, and he is board-certified in obstetrics and gynecology. Douso Report 2 [ECF No. 29-1]. He has extensive experience with BSC's products for treating SUI and POP, including use of the Prefyx and Uphold mesh sling devices. *Id.* Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including implantation of the defendant's polypropylene mesh devices. *Id.* Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc.*, 878 F.2d at 799. I **FIND** that Dr. Douso's extensive experience qualifies him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices.

With respect to reliability, the plaintiffs challenge Dr. Douso's opinion on the physical properties of mesh—specifically that there is no evidence the device in question degrades, contracts, or elicits a continuous foreign body response. Dr. Douso claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, supplemented by reliance on medical and scientific literature. On the one hand, these are reasonable bases from which to form an expert opinion. On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations or the

methodology. Further, I have no basis to assess claims that Dr. Douso's observations are supported by the scientific literature.

For the reasons discussed in my analysis of Dr. Culligan and Dr. Goldberg, I am without sufficient information at this time to determine the reliability of Dr. Douso's opinions on the physical properties of mesh. Accordingly, the I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

Therefore, for the reasons given above, the plaintiff's Motion to Exclude the Opinions and Testimony of Michael Douso, M.D. [ECF No. 29] is **GRANTED in part, DENIED in part,** and **RESERVED in part**.

VI. Effect of *Daubert* Ruling

I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their potential admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility at trial. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VII. Conclusion

For the reasons discussed above, my rulings on BSC's motions are as follows: Motion to Exclude the Opinions and Testimony of Niall Galloway, M.D. [ECF No. 32] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [ECF No. 30] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D.

[ECF No. 33] is **GRANTED**; Motion to Limit the Opinions and Testimony of Bobby L. Shull, M.D. [ECF No. 39] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [ECF No. 40] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [ECF No. 43] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**; Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [ECF No. 44] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [ECF No. 45] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Dionysios Veronikis, M.D. [ECF No. 36] is **GRANTED in part and DENIED in part**; Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [ECF No. 47] is **GRANTED in part** and **DENIED in part**; Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [ECF No. 55] is **GRANTED**; and Motion to Strike and Exclude the Opinions and Testimony of David Goldfarb, M.D. [ECF No. 41] is **GRANTED in part and DENIED in part**.

My rulings on the plaintiff's motions are as follows: Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [ECF No. 34] is **RESERVED**; Motion to Exclude Certain Opinions and Testimony of Dr. Patrick Culligan [ECF No. 38] is **GRANTED in part**, **DENIED in part,** and **RESERVED in part**; Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 37] is **DENIED as moot**; Amended Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 48] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. [ECF No. 35] is **GRANTED in part, DENIED in part,** and **RESERVED**

in part; Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 53] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 54] is **DENIED**; and Motion to Exclude the Opinions and Testimony of Michael Douso, M.D. [ECF No. 29] is **GRANTED in part, DENIED in part,** and **RESERVED in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 19, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE